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Centers for Medicare & Medicaid Services

42 CFR Part 419

Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Rates; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 419

[CMS–1427–FC]

RIN 0938–AM75

Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period revises the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and changes arising from our continuing experience with this system and to implement certain related provisions of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003. In addition, the final rule with comment period describes final changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system. These changes are applicable to services furnished on or after January 1, 2005.

In this final rule with comment period, we are responding to public comments received on the January 6, 2004 interim final rule with comment period relating to MMA provisions that were effective January 1, 2004, and finalizing those policies. Further, we are responding to public comments received on the November 7, 2003 final rule with comment period pertaining to the ambulatory payment classification assignment of Healthcare Common Procedure Coding System (HCPCS) codes identified in Addendum B of that rule with the new interim (NI) comment indicators (formerly referred to as condition codes).

DATES: *Effective Date:* This final rule with comment period is effective on January 1, 2005.

Comment Date: We will consider comments on the ambulatory payment classification assignments of HCPCS codes identified in Addendum B with new interim comment codes and other areas specified throughout this preamble, if we receive them at the appropriate address, as provided below no later than 5 p.m. on January 14, 2005.

ADDRESSES: In commenting, please refer to file code CMS–1427–FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. Electronically

You may submit electronic comments to *http://www.cms.hhs.gov/regulations/ecomments* (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word).

2. By Mail

You may mail written comments (one original and two copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1427–FC, P.O. Box 8010, Baltimore, MD 21244–8018.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By Hand or Courier

If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. After the close of the comment period, CMS posts all electronic comments received before the close of the comment period on its public website. Written comments received timely will be available for public inspection as they are received, generally beginning approximately 4 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (410) 786–7195.

FOR FURTHER INFORMATION CONTACT: Dana Burley, (410) 786–0378, Outpatient prospective payment issues and Suzanne Asplen, (410) 786–4558, Partial hospitalization and community mental health center issues.

SUPPLEMENTARY INFORMATION:

Availability of Copies and Electronic Access

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, PO Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 (or toll-free at 1–888–293–6498) or by faxing to (202) 512–2250. The cost for each copy is $10. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

This **Federal Register** document is also available from the **Federal Register** online database through *GPO Access,* a service of the U.S. Government Printing Office. The Web site address is: *http://www.gpoaccess.gov/fr/index.html.*

Alphabetical List of Acronyms Appearing in the Final Rule With Comment Period

ACEP—American College of Emergency Physicians
AHA—American Hospital Association
AHIMA—American Health Information Management Association
AMA—American Medical Association
APC—Ambulatory payment classification
AMP—Average manufacturer price
ASP—Average sales price
ASC—Ambulatory surgical center
AWP—Average wholesale price
BBA—Balanced Budget Act of 1997, Public Law 105–33
BIPA—Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Public Law 106–554
BBRA—Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Public Law 106–113
CAH—Critical access hospital
CCR—(Cost center specific) cost-to-charge ratio
CMHC—Community mental health center

CMS—Centers for Medicare & Medicaid Services (formerly known as the Health Care Financing Administration)
CORF—Comprehensive outpatient rehabilitation facility
CPT—[Physicians'] Current Procedural Terminology, Fourth Edition, 2004, copyrighted by the American Medical Association
CRNA—Certified registered nurse anesthetist
CY—Calendar year
DMEPOS—Durable medical equipment, prosthetics, orthotics, and supplies
DMERC—Durable medical equipment regional carrier
DRG—Diagnosis-related group
DSH—Disproportionate share hospital
EACH—Essential Access Community Hospital
E/M—Evaluation and management
EPO—Erythropoietin
ESRD—End-stage renal disease
FACA—Federal Advisory Committee Act, Public Law 92–463
FDA—Food and Drug Administration
FI—Fiscal intermediary
FSS—Federal Supply Schedule
FY—Federal fiscal year
HCPCS—Healthcare Common Procedure Coding System
HCRIS—Hospital Cost Report Information System
HHA—Home health agency
HIPAA—Health Insurance Portability and Accountability Act of 1996, Public Law 104–191
ICD–9–CM—International Classification of Diseases, Ninth Edition, Clinical Modification
IME—Indirect medical education
IPPS—(Hospital) inpatient prospective payment system
IVIG—Intravenous immune globulin
LTC—Long-term care
MedPAC—Medicare Payment Advisory Commission
MDH—Medicare-dependent hospital
MMA—Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173
MSA—Metropolitan Statistical Area
NCCI—National Correct Coding Initiative
NCD—National Coverage Determination
OCE—Outpatient code editor
OMB—Office of Management and Budget
OPD—(Hospital) outpatient department
OPPS—(Hospital) outpatient prospective payment system
PET—Positron Emission Tomography
PHP—Partial hospitalization program
PM—Program memorandum
PPI—Producer Price Index
PPS—Prospective payment system
PPV—Pneumococcal pneumonia (virus)
PRA—Paperwork Reduction Act
QIO—Quality Improvement Organization
RFA—Regulatory Flexibility Act
RRC—Rural referral center
SBA—Small Business Administration
SCH—Sole community hospital
SDP—Single drug pricer
SI—Status indicator
TEFRA—Tax Equity and Fiscal Responsibility Act of 1982, Public Law 97–248
TOPS—Transitional outpatient payments
USPDI—United States Pharmacopoeia Drug Information

To assist readers in referencing sections contained in this document, we are providing the following outline of contents:

Outline of Contents

I. Background

A. Legislative and Regulatory Authority for the Outpatient Prospective Payment System

When the Medicare statute was originally enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), enacted on August 5, 1997, added section 1833(t) to the Social Security Act (the Act) authorizing implementation of a PPS for hospital outpatient services. The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), enacted on November 29, 1999, made major changes that affected the hospital outpatient PPS (OPPS). The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554), enacted on December 21, 2000, made further changes in the OPPS. Section 1833(t) of the Act was also recently amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Public Law 108–173, enacted on December 8, 2003 (these amendments are discussed later under section I.E. of this final rule with comment period). The OPPS was first

implemented for services furnished on or after August 1, 2000. Implementing regulations for the OPPS are located at 42 CFR Part 419.

Under the OPPS, we pay for hospital outpatient services on a rate-per-service basis that varies according to the ambulatory payment classification (APC) group to which the service is assigned. We use Healthcare Common Procedure Coding System (HCPCS) codes (which include certain Current Procedural Terminology (CPT) codes) and descriptors to identify and group the services within each APC group. The OPPS includes payment for most hospital outpatient services, except those identified in section I.B. of this final rule with comment period. Section 1833(t)(1)(B)(ii) of the Act provides for Medicare payment under the OPPS for certain services designated by the Secretary that are furnished to inpatients who have exhausted their Part A benefits or who are otherwise not in a covered Part A stay. In addition, the OPPS includes payment for partial hospitalization services furnished by community mental health centers (CMHCs).

The OPPS rate is an unadjusted national payment amount that includes the Medicare payment and the beneficiary copayment. This rate is divided into a labor-related amount and a nonlabor-related amount. The labor-related amount is adjusted for area wage differences using the inpatient hospital wage index value for the locality in which the hospital or CMHC is located.

All services and items within an APC group are comparable clinically and with respect to resource use (section 1833(t)(2)(B) of the Act). In accordance with section 1833(t)(2) of the Act, subject to certain exceptions, services and items within an APC group cannot be considered comparable with respect to the use of resources if the highest median (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost for an item or service within the same APC group (referred to as the ''2 times rule''). In implementing this provision, we use the median cost of the item or service assigned to an APC group.

Special payments under the OPPS may be made for new technology items and services in one of two ways. Section 1833(t)(6) of the Act provides for temporary additional payments or ''transitional pass-through payments'' for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and categories of medical devices for at least 2 but not more than 3 years. For new technology services that are not eligible for pass-through payments and for which we lack sufficient data to appropriately assign them to a clinical APC group, we have established special APC groups based on costs, which we refer to as APC cost bands. These cost bands allow us to price these new procedures more appropriately and consistently. Similar to pass-through payments, these special payments for new technology services are also temporary; that is, we retain a service within a new technology APC group until we acquire adequate data to assign it to a clinically appropriate APC group.

B. Excluded OPPS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. While most hospital outpatient services are payable under the OPPS, section 1833(t)(1)(B)(iv) of the Act excluded payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. The Secretary exercised the broad authority granted under the statute to exclude from the OPPS those services that are paid under fee schedules or other payment systems. Such excluded services include, for example, the professional services of physicians and nonphysician practitioners paid under the Medicare Physician Fee Schedule; laboratory services paid under the clinical diagnostic laboratory fee schedule; services for beneficiaries with end-stage renal disease (ESRD) that are paid under the ESRD composite rate; and services and procedures that require an inpatient stay that are paid under the hospital inpatient prospective payment system (IPPS). We set forth the services that are excluded from payment under the OPPS in § 419.22 of the regulations.

Under § 419.20 of the regulations, we specify the types of hospitals and entities that are excluded from payment under the OPPS. These excluded entities include Maryland hospitals, but only for services that are paid under a cost containment waiver in accordance with section 1814(b)(3) of the Act; critical access hospitals (CAHs); hospitals located outside of the 50 States, the District of Columbia, and Puerto Rico; and Indian Health Service hospitals.

C. Prior Rulemaking

On April 7, 2000, we published in the **Federal Register** a final rule with comment period (65 FR 18434) to implement a prospective payment system for hospital outpatient services. The hospital OPPS was first implemented for services furnished on or after August 1, 2000. Section 1833(t)(9) of the Act requires the Secretary to review certain components of the OPPS not less often than annually and to revise the groups, relative payment weights, and other adjustments to take into account changes in medical practice, changes in technology, and the addition of new services, new cost data, and other relevant information and factors. Since implementing the OPPS, we have published final rules in the **Federal Register** annually to implement statutory requirements and changes arising from our experience with this system. For a full discussion of the changes to the OPPS, we refer readers to these **Federal Register** final rules.[1]

On November 7, 2003, we published a final rule with comment period in the **Federal Register** (68 FR 63398) that revised the OPPS to update the payment weights and conversion factor for services payable under the calendar year (CY) 2004 OPPS on the basis of claims data from April 1, 2002 through December 31, 2002. In this final rule with comment period, we are finalizing the APC assignments and addressing public comments received pertaining to the new interim HCPCS codes listed in Addendum B of the November 7, 2003 final rule with comment period identified by new interim (NI) comment indicators (formerly referred to as condition codes). Subsequent to publishing the November 7, 2003 final rule with comment period, we published a correction of the final rule with comment period on December 31, 2003 (68 FR 75442). That December 31, 2003 document corrected technical errors in the November 7, 2003 final rule with comment period and included responses to a number of public comments that were inadvertently omitted from the November 2003 final rule with comment period.

On January 6, 2004, we published in the **Federal Register** an interim final rule with comment period (69 FR 820) that implemented provisions of Public Law 108–173 that affected payments made under the OPPS, effective January 1, 2004. We are finalizing this interim

[1] Interim final rule with comment period, August 3, 2000 (65 FR 47670); interim final rule with comment period, November 13, 2000 (65 FR 67798); final rule and interim final rule with comment period, November 2, 2001 (66 FR 55850 and 55857); final rule, November 30, 2001 (66 FR 59856); final rule, December 31, 2001 (66 FR 67494); final rule, March 1, 2002 (67 FR 9556); final rule, November 1, 2002 (67 FR 66718); final rule with comment period, November 7, 2003 (68 FR 63398); and interim final rule with comment period, January 6, 2004 (69 FR 820).

final rule and addressing public comments associated with that rule in this final rule with comment period.

D. APC Advisory Panel

1. Authority of the APC Panel

Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of the BBRA of 1999, requires that we consult with an outside panel of experts to review the clinical integrity of the payment groups and weights under the OPPS. The Advisory Panel on APC Groups (the APC Panel), discussed under section I.D.2. of this preamble, fulfills this requirement. The Act further specifies that the Panel will act in an advisory capacity. This expert panel, which is to be composed of 15 representatives of providers subject to the OPPS (currently employed full-time, not consultants, in their respective areas of expertise), reviews and advises us about the clinical integrity of the APC groups and their weights. The APC Panel is not restricted to using our data and may use data collected or developed by organizations outside the Department in conducting its review.

2. Establishment of the APC Panel

On November 21, 2000, the Secretary signed the charter establishing the Advisory Panel on APC Groups. The APC Panel is technical in nature and is governed by the provisions of the Federal Advisory Committee Act (FACA), as amended (Public Law 92–463). On November 1, 2002, the Secretary renewed the charter. The renewed charter indicates that the APC Panel continues to be technical in nature, is governed by the provisions of the FACA, may convene up to three meetings per year, and is chaired by a Federal official.

Originally, in establishing the APC Panel, we solicited members in a notice published in the **Federal Register** on December 5, 2000 (65 FR 75943). We received applications from more than 115 individuals who nominated either colleagues or themselves. After carefully reviewing the applications, we chose 15 highly qualified individuals to serve on the APC Panel. Because of the loss of four APC Panel members due to the expiration of terms of office on March 31, 2004, we published a **Federal Register** notice on January 23, 2004 (69 FR 3370) that solicited nominations for APC Panel membership. From the 24 nominations that we received, we chose four new members. The entire APC Panel membership is identified on the CMS Web site at *http://www.cms.hhs.gov/faca/apc/apcmem.asp.*

3. APC Panel Meetings and Organizational Structure

The APC Panel first met on February 27, February 28, and March 1, 2001. Since that initial meeting, the APC Panel has held five subsequent meetings, with the last meeting taking place on September 1, 2, and 3, 2004. Prior to each of these biennial meetings, we published a notice in the **Federal Register** to announce each meeting and, when necessary, to solicit nominations for APC Panel membership. For a more detailed discussion about these announcements, refer to the following **Federal Register** notices: December 5, 2000 (65 FR 75943), December 14, 2001 (66 FR 64838), December 27, 2002 (67 FR 79107), July 25, 2003 (68 FR 44089), and December 24, 2003 (68 FR 74621), and August 5, 2004 (69 FR 47446).

During these meetings, the APC Panel established its operational structure that, in part, includes the use of three subcommittees to facilitate its required APC review process. Currently, the three subcommittees are the Data Subcommittee, the Observation Subcommittee, and the Packaging Subcommittee. The Data Subcommittee is responsible for studying the data issues confronting the APC Panel and for recommending viable options for resolving them. This subcommittee was initially established on April 23, 2001, as the Research Subcommittee and reestablished as the Data Subcommittee on April 13, 2004. The Observation Subcommittee, which was established on June 24, 2003, and reestablished with new members on March 8, 2004, reviews and makes recommendations to the APC Panel on all issues pertaining to observation services paid under the OPPS, such as coding and operational issues. The Packaging Subcommittee, which was established on March 8, 2004, studies and makes recommendations on issues pertaining to services that are not separately payable under the OPPS but are bundled or packaged APC payments. Each of these subcommittees was established by a majority vote of the APC Panel during a scheduled APC Panel meeting. All subcommittee recommendations are discussed and voted upon by the full APC Panel.

For a detailed discussion of the APC Panel meetings, refer to the hospital OPPS final rules cited in section I.C. of this preamble. Full discussions of the APC Panel's February 2004 and September 2004 meetings and the resulting recommendations are included in sections II., III., IV., V., and VI. of this preamble under the appropriate subject headings.

E. Provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

On December 8, 2003, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Public Law 108–173, was enacted. Public Law 108–173 made changes to the Act relating to the Medicare OPPS. In a January 6, 2004 interim final rule with comment period, we implemented provisions of Public Law 108–173 relating to the OPPS that were effective for CY 2004. In this final rule with comment period, we are responding to public comments received on the January 6, 2004 interim final rule and finalizing that rule. In addition, in this final rule with comment period, we are implementing the following sections of Public Law 108–173 that are effective for CY 2005:

- Section 611, which provides for Medicare coverage of an initial preventive physical examination under Part B, subject to the applicable deductible and coinsurance, as an outpatient department (OPD) service payable under the OPPS. The provisions of section 611 apply to services furnished on or after January 1, 2005, but only for individuals whose coverage period under Medicare Part B begins on or after that date.
- Section 614, which provides that screening mammography and diagnostic mammography services are excluded from payment under the OPPS. This amendment applies to screening mammography services furnished on or after the date of enactment of Public Law 108–173 (that is, December 8, 2003), and in the case of diagnostic mammography, to services furnished on or after January 1, 2005.
- Section 621(a)(1), which requires special classification of certain separately paid radiopharmaceutical agents and drugs or biologicals, and specifies the pass-through payment percentages, effective for services furnished on or after January 1, 2005, for the three categories of ''specified covered OPD drugs'' defined in the statute: sole source drug; innovator multiple source drug; and noninnovator multiple source drug. In addition, payment for these drugs for CYs 2004 and 2005 does not have to be made in a budget neutral manner.
- Section 621(a)(2), which specifies the reduced threshold for the establishment of separate APCs with respect to drugs or biologicals from $150 to $50 per administration for drugs and biologicals furnished in CYs 2005 and 2006.

• Section 621(a)(3), which excludes separate drug APCs from outlier payments. Specifically, no additional payment will be made in the case of APC groups established separately for drugs and biologicals.

• Section 621(b), which requires that all devices of brachytherapy consisting of a seed or seeds (or radioactive source) furnished on or after January 1, 2004, and before January 1, 2007, be paid based on the hospital's charges for each device, adjusted to cost. This provision also requires that these brachytherapy services be excluded from outlier payments.

F. Summary of the Provisions of the August 16, 2004 Proposed Rule

On August 16, 2004, we published a proposed rule in the **Federal Register** (69 FR 50447) that set forth proposed changes to the Medicare hospital OPPS and to implement provisions of Public Law 108–173 specified in section I.E. of this preamble that would be effective for services furnished on or after January 1, 2005. The following is a summary of the major changes that we proposed to make:

1. Changes to the APC Groups

As required by section 1833(t)(9)(A) of the Act, we proposed the annual update of the APC groups and the relative payment weights. This section also requires that we consult with an outside panel of experts, the Advisory Panel on APC Groups, to review the clinical integrity of the groups and weights under the OPPS. Based on analyses of Medicare claims data and recommendations of the APC Panel, we proposed to establish a number of new APCs and to make changes to the assignment of HCPCS codes under a number of existing APCs.

We also discussed the application of the 2 times rule and proposed exceptions to it; coding for stereotactic radiosurgery services; the proposed movement of procedures from the new technology APCs; the proposed changes to the list of procedures that will be paid as inpatient services; and the proposed addition of new procedure codes to the APCs.

2. Recalibrations of APC Relative Payment Weights

In the proposed rule, we discussed the methodology used to recalibrate the proposed APC relative payment weights and set forth the proposed recalibration of the relative weights for CY 2005.

3. Payment Changes for Devices

In the proposed rule, we discussed proposed changes to the pass-through payment for devices and the methodology used to reduce, if applicable, transitional pass-through payments to offset costs packaged into APC groups.

4. Payment Changes for Drugs, Biologicals, Radiopharmaceutical Agents, and Blood and Blood Products

In the proposed rule, we discussed our proposed payment changes for drugs, biologicals, radiopharmaceutical agents, and blood and blood products.

5. Estimated Transitional Pass-Through Spending in CY 2005 for Drugs, Biologicals, and Devices

In the proposed rule, we discussed the proposed methodology for measuring whether there should be an estimated pro rata reduction for transitional pass-through drugs, biologicals, and devices for CY 2005.

6. Other Policy Decisions and Proposed Policy Changes

In the proposed rule, we presented our proposals for CY 2005 regarding the following:

• Update of statewide default cost-to-charge ratios (CCRs).

• A conforming change to the regulation relating to the use of the first available cost reporting period ending after 1996 and before 2001 for determining a provider's payment-to-cost ratio to calculate transitional corridor payments for hospitals paid under the OPPS that did not have a 1996 cost report.

• Changes in the status indicators and comment indicators assigned to APCs for CY 2005.

• Elimination of the diagnostic tests criteria as a requirement for hospitals to qualify for separate payment of observation services under APC 0339 (Observation) and changes to the guidelines to hospitals for counting patients' time spent in observation care.

• Payment under the OPPS for certain procedures currently assigned to the inpatient list.

• Strategy for giving the public notice of new implementation guidelines for new evaluation and management codes.

• Addition of three new HCPCS codes and descriptors for brachytherapy sources that would be paid separately, pursuant to Public Law 108–173.

• Modification of the HCPCS code descriptors for brachytherapy source descriptors for which units of payment are not already delineated.

• Payment for services furnished emergently to an outpatient who dies before admission to a hospital as an inpatient.

7. Conversion Factor Update for CY 2005

As required by section 1833(5)(3)(C)(ii) of the Act, in the proposed rule, we proposed to update the conversion factor used to determine payment rates under the OPPS for CY 2005.

8. Wage Index Changes for CY 2005

In the proposed rule, we discussed the proposed retention of our current policy to apply the IPPS wage indices to wage adjust the APC median costs in determining the OPPS payment rate and the copayment standardized amount. These indices reflect major changes for CY 2005 relating to hospital labor market areas as a result of OMB revised definitions of geographical statistical areas; hospital reclassifications and redesignations, including the one-time reclassifications under section 508 of Public Law 108–173; and the wage index adjustment based on commuting patterns of hospital employees under section 505 of Public Law 108–173.

9. Determination of Payment Rates and Outlier Payments for CY 2005

In the proposed rule, we discussed how APC payment rates are calculated and how the payment rates are adjusted to reflect geographic differences in labor-related costs. We also discussed proposed changes in the way we would calculate outlier payments for CY 2005.

10. Regulatory Impact Analysis

In the proposed rule, we set forth our analysis of the impact that the proposed changes would have on affected hospitals and CMHCs.

G. Public Comments Received on the August 16, 2004 Proposed Rule

We received over 550 timely pieces of correspondence containing multiple comments on the August 16, 2004 proposed rule. Summaries of the public comments and our responses to those comments are set forth in the various sections of this preamble under the appropriate heading.

We received a number of general public comments on our proposed changes to the OPPS for CY 2005.

Comment: Some commenters were concerned about the extent to which OPPS payment rates have fluctuated from year to year. Because Medicare payment is a very significant portion of income for most hospitals, they stated that the instability in the OPPS payment rates makes it difficult for hospitals to plan and budget. They indicated that there is a tremendous degree of variation across APCs in terms of payment to cost ratios and that they

would expect that after three years of operating the OPPS, the payment to cost ratios would be much more stable. One commenter offered to share analysis of payment to cost ratios with CMS. Commenters stated that such variation in payments compared to costs puts full-service hospitals and their communities at risk because limited-service, or ''niche'' providers can easily identify and redirect patients with more lucrative APCs to their facilities, leaving full-service hospitals with a disproportionate share of patients who receive services that are assigned to the underpaid APCs.

Response: We recognize hospitals' need for stability in payments for hospital outpatient services. We would appreciate receiving studies of the extent to which there is variation across APCS in terms of payment to cost ratios across the multiple years of the OPPS to aid us in assessing factors that might contribute to instability in the payment rates.

Comment: One commenter indicated that the entire OPPS is underfunded, as it pays only 87 cents of every dollar of hospital outpatient care provided to Medicare beneficiaries. The commenter stated that it will continue to work with Congress to address inadequate payment rates and updates in order to ensure access to hospital-based outpatient services for Medicare beneficiaries.

Response: Our early analyses indicated that the OPPS was, in its inception, based on payment that was less than cost due to statutory reductions in payment for hospital outpatient costs prior to the enactment of the Balanced Budget Act of 1997, which authorized the current OPPS. We agree that the commenter will need to work with Congress to change certain fundamental features of the OPPS. For example, the base amounts upon which the OPPS was established, the rules concerning budget neutrality, and subsequent out-year adjustments such as annual reductions in coinsurance and adjustments to outlier and pass-through payment allocations are established in statute and, as such, would require legislation to amend.

Comment: One commenter objected to the use of the display date to start the 60-day comment period for the proposed rule. The commenter stated that the display copy did not contain all of the information included in the proposed rule, such as the comment due date, and did not satisfy the statute's requirement that the notice of proposed rulemaking be published in the **Federal Register**, with provision for a 60-day comment period. The commenter indicated that the use of the display date to start the comment period gives reviewers too short a period of time to comment properly and also, in this case, gives CMS an inadequate period of time to review the comments and prepare the final rule. The commenter urged CMS to publish a proposed rule no later than late July to provide more time for CMS to consider public comments.

Response: While the law requires that we provide a 60-day public comment period and that the notice of proposed rulemaking be published in the **Federal Register**, it does not require that the date of **Federal Register** publication be the first day of the comment period. The two requirements are independent. We post the proposed rule on the CMS Web site on the date of display of the proposed rule at the **Federal Register**, thereby making the proposed rule far more easily available to the public than was the case when the only public dissemination was publication in the **Federal Register**, and satisfying the requirement for a 60-day comment period. By making the proposed rule available on the CMS Web site (as well as at the **Federal Register**), we provided the public with access to not only the proposed rule but also to all of the supporting files and documents cited in the proposed rule in a manner that can be used for analysis. We note that the computer files posted on the Web site can be manipulated for independent analysis. Therefore, we believe that beginning the comment period for the proposed rule with the display date at the **Federal Register**, and posting the proposed rule and data files on the CMS Web site on the display date, fully complies with the statute and provides a far better opportunity for the public to have meaningful input than the past practice under which the comment period began with the publication date in the **Federal Register** a week or longer after the display date and no other data in any other form was furnished.

With respect to the publication date of the proposed rule, we publish the proposed rule as soon as it is practicable for us to do so. Our process for development of the proposed rule begins with a winter meeting of the APC Panel based on the earliest possible data analysis for the forthcoming year. We then pull claims for the period ending December of the data year and also pull cost report data for development of CCRs to apply to the claims data. This step cannot be started until approximately March 1 of the year and the development of the proposed rule data takes considerable time as there are many analyses to be performed and decisions to be made before each stage of data development can be undertaken. We have to balance the need to improve the process and to deal with each year's special issues with the need to issue a proposed rule in sufficient time to permit the public to comment and to permit us sufficient time to review the comments and develop the final rule. Each year we review the timeline and process to determine how we can best achieve that balance, while ensuring that we issue the best possible proposed rule for public comment.

H. Public Comments Received on the January 6, 2004 Interim Final Rule With Comment Period

We received approximately 40 timely pieces of correspondence containing multiple comments on the MMA provisions relating to payment for drugs and brachytherapy under the OPPS that were included in the January 6, 2004 interim final rule with comment period. Summaries of the public comments and our responses to those comments are set forth in sections V. and VII.G. of this preamble under the appropriate heading.

I. Public Comments Received on the November 7, 2003 Final Rule With Comment Period

We received 25 timely pieces of correspondence on the November 7, 2003 final rule with comment period, some of which contained multiple comments on the APC assignment of HCPCS codes identified with the new interim condition indicators (now referred to as condition codes) in Addendum B of that final rule with comment period. Summaries of the public comments and our responses to those comments are set forth in various sections of this preamble under the appropriate subject areas.

II. Changes Related to Ambulatory Payment Classifications (APCs)

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient services. Section 1833(t)(2)(B) provides that this classification system may be composed of groups of services, so that services within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we developed a grouping classification system, referred to as the Ambulatory Payment Classification Groups (or APCs), as set forth in § 419.31 of the regulations. We use Level I and Level II Healthcare Common Procedure Coding System (HCPCS) codes and descriptors to identify and group the services within each APC. The APCs are organized such that each

group is homogeneous both clinically and in terms of resource use. (However, new technology APCs that are temporary groups for certain approved services are structured based on cost rather than clinical homogeneity.) Using this classification system, we have established distinct groups of surgical, diagnostic, and partial hospitalization services, and medical visits. Because of the transitional pass-through provisions, we also have developed separate APC groups for certain medical devices, drugs, biologicals, radiopharmaceuticals, and devices of brachytherapy.

We have packaged into each procedure or service within an APC group the cost associated with those items or services that are directly related and integral to performing a procedure or furnishing a service. Therefore, we would not make separate payment for packaged items or services. For example, packaged items and services include: Use of an operating, treatment, or procedure room; use of a recovery room; use of an observation bed; anesthesia; medical/surgical supplies; pharmaceuticals (other than those for which separate payment may be allowed under the provisions discussed in section V. of this preamble); and incidental services such as venipuncture. Our packaging methodology is discussed in section IV.B.3. of this final rule with comment period.

A. APC Changes: General

Under the OPPS, we pay for hospital outpatient services on a rate-per-service basis that varies according to the APC group to which the service is assigned. Each APC weight represents the median hospital cost of the services included in that APC relative to the median hospital cost of the services included in APC 0601, Mid-Level Clinic Visits. The APC weights are scaled to APC 0601 because a mid-level clinic visit is one of the most frequently performed services in the outpatient setting.

Section 1833(t)(9)(A) of the Act requires the Secretary to review the components of the OPPS not less than annually and to revise the groups and relative payment weights and make other adjustments to take into account changes in medical practice, changes in technology, and the addition of new services, new cost data, and other relevant information and factors. Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of the BBRA of 1999, also requires the Secretary, beginning in CY 2001, to consult with an outside panel of experts to review the APC groups and the relative payment weights.

Finally, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median (or mean cost, if elected by the Secretary) for an item or service in the group is more than 2 times greater than the lowest median cost for an item or service within the same group (referred to as the ''2 times rule''). We use the median cost of the item or service in implementing this provision. The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as low volume items and services.

Section 419.31 of the regulations sets forth the requirements for the APC system and the determination of the payment weights. In this section, we discuss the changes that we proposed to the APC groups; the APC Panel's review and recommendations from the February 2004 meeting and our proposals in response to those recommendations; the application of the 2 times rule and proposed exceptions to it; coding for stereotactic radiosurgery services; the proposed movement of procedures from the new technology APCs; the proposed changes to the inpatient list; and the proposed additions of new procedures codes to the APCs. In addition, in this section under the appropriate subject heading, we present the APC Panel's review and recommendations of items discussed at the September 1, 2, and 3, 2004 meeting held after publication of the proposed rule and our final decisions on these recommendations. We then present our final policies that are effective for CY 2005.

B. APC Panel Review and Recommendations

1. February 2004 Panel Meeting

As stated above, the APC Panel held its first 2004 meeting on February 18, 19, and 20, 2004, to discuss the revised APCs for the CY 2005 OPPS. In preparation for that meeting, we published a notice in the **Federal Register** on December 24, 2003 (68 FR 74621), to announce the location, date, and time of the meeting; the agenda items; and the fact that the meeting was open to the public. In that notice, we solicited public comment specifically on the items included on the agenda for that meeting. We also provided information about the APC Panel meeting on the CMS Web site: *http://www.cms.hhs.gov/faca/apc/panel.*

Oral presentations and written comments submitted for the February 2004 APC Panel meeting met, at a minimum, the adopted guidelines for presentations set forth in the **Federal Register** document (68 FR 74621). In conducting its APC review, the APC Panel heard testimony and received evidence in support of the testimonies from a number of interested parties. For the February 2004 deliberations, the APC Panel used hospital outpatient claims data for the period January 1, 2003, through September 30, 2003, that provided, at a minimum, median costs for the APC structure in place in CY 2004 and that was based on CCRs used for setting the CY 2004 payment rates. The data set presented to the APC Panel represented 9 months of the CY 2003 data that we proposed to use to recalibrate the APC relative weights and to calculate the proposed APC payment rates for CY 2005. In sections II.B.4. through 7. and sections II.C. through I. of this preamble, we summarize the APC issues discussed during the APC Panel's February 2004 meeting, the Panel's recommendations, the proposals that we included in the August 16, 2004 proposed rule, our proposals with respect to those recommendations, and the policies that we are finalizing for CY 2005 in this final rule with comment period.

2. September 2004 Panel Meeting

As stated earlier, the APC Panel held its second 2004 meeting on September 1–3, 2004. In preparation for that meeting, we published a notice in the **Federal Register** on August 5, 2004 (69 FR 47446) to announce the location, date, and time of the meeting, the agenda items, and the fact that the meeting was open to the public. In that notice, we solicited public comments specifically on the items included on the agenda for that meeting. During the September 2004 APC Panel meeting, the APC Panel heard testimony on a number of the proposed changes in APCs included in the August 16, 2004 proposed rule. We are summarizing the topics that were discussed at the September 2004 Panel meeting and the APC Panel's recommendations on each topic in the chart below. We have included references to the appropriate section of this preamble for the more detailed discussion of each recommendation.

For the September 2004 deliberations, the APC Panel used the hospital outpatient claims data that we used in developing the proposed rule; that is, data for the period of January 1, 2003,

through December 31, 2003, including updated CCRs.

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Summary of APC Panel Recommendations from September 2004 Meeting

Recommendation	For Discussion, see Preamble Section
The APC Panel recommended that CMS should--	Section II.B.6
1. Continue its exploration of ways to increase the number of multiple procedure claims that can be used for OPPS ratesetting.	Section III.A.1
2. Post the crosswalk of revenue codes to cost centers on the OPPS website.	Section V.H
3. Assign a modifier to CPT codes 36540, 36600, 51701, and 97602 to facilitate identification of claims on which any of those is the only payable code on the date of service.	Section II.B.7
4. Not change the status indicator for CPT code 76937.	Section II.B.7
5. Allow separate payment for observation services even when cardiac catheterization is performed on the same day.	Section VII.D
6. Expand the list of diagnoses eligible for observation services.	Section VII. D
7. Solicit input on the inpatient list from professional organizations.	Section II.G
8. Maintain payment for low-volume blood products for CY 2005 at the CY 2004 level.	Section V.I
9. Use external data as a basis for setting payment rates for low-volume blood products.	Section V.I
10. Evaluate whether or not current statutes allow the extension of pass-through status for embolization protective system (HCPCS code C1884).	Section IV.A.2
11. Require that C-codes be reported for all devices associated with a C-code.	Section III.C.4
12. Retain the CY 2004 configuration of APCs 0385 and 0386.	Section III.C.1
13. Except for APCs 0418 and 0425, make adjustments to the medians for the device-dependent APCs listed in Table 19 of the August 16, 2004 proposed rule that increase or decrease by 5 percent for CY 2005 compared to CY 2004.	Section III.C.4
14. Assign CPT code 58563 and HCPCS code 0009T to APC 0387.	Section II.C.13
15. Evaluate the APC assignments for CPT codes 36555 through 36597 for discussion at the first CY 2005 (winter) meeting of the APC Panel.	Section II.C.13
16. Maintain CPT codes 77523 and 77525 in the new technology APC for CY 2005.	Section II. F.3
17. Assign status indicator K to HCPCS code J2790	Section V.B.2

3. Contents of This Section of the Preamble

The discussion in this section II.B. of this final rule with comment period is limited to APC changes regarding APCs other than those that violate the 2 times rule and those that represent drugs, biologicals, and transitional pass-through devices, or those that are new technology APCs. The specific APC Panel review and recommendations applicable to those APCs are discussed in sections II.C., IV., III., and II.F., respectively, of the preamble to this final rule with comment period.

4. APC 0018: Biopsy of Skin/Puncture of Lesion

During the February 2004 APC Panel meeting, one presenter recommended moving CPT tracking codes 0046T (Catheter lavage, mammary duct(s)) and 0047T (Each additional duct) from APC 0018 and placing them in an APC that more accurately reflects each of the procedures. The APC Panel recommended that we reassign CPT codes 0046T and 0047T to APC 0021, Level III Excision/Biopsy.

In the August 16, 2004 proposed rule, we proposed to accept the APC Panel's recommendation. We did not receive any public comments on our proposal. Therefore, we are adopting as final, without modification, our proposal to reassign CPT codes 0046T and 0047T to APC 0021.

5. Level I and II Arthroscopy

APC 0041: Level I Arthroscopy

APC 0042: Level II Arthroscopy

We testified before the APC Panel at its February 2004 meeting regarding a comment that we received in 2003 requesting that we reassign CPT code 29827 (Arthroscopy, shoulder with rotator cuff repair) from APC 0041 to APC 0042, based on its similarity to CPT 29826 (Arthroscopy, shoulder decompression of subacromial space with partial acromioplasty without coracoacromial release). Our clinical staff considered the request and determined that APCs 0041 and 0042 should be reconfigured to improve clinical homogeneity. An APC Panel presenter provided evidence to support moving CPT code 29827 to an APC that would more accurately recognize the complexity of that procedure. We requested the APC Panel's recommendation regarding a total revision of these two APCs.

The APC Panel recommended that we reevaluate the codes in APCs 0041 and 0042 and propose restructuring that would improve the clinical homogeneity in the two APCs.

In the August 16, 2004 proposed rule, we proposed to accept the APC Panel's recommendation and to revise APCs 0041 and 0042 as presented in Tables 1 and 2 of that proposed rule. We received one public comment on our proposed restructuring.

Comment: One commenter requested that we move code 0014T from APC 0041 to APC 0042. The commenter provided information in support of its belief that the procedure more accurately matches the clinical work and resource inputs of APC 0042 than of APC 0041.

Response: We agree with the commenter and are assigning the procedure to APC 0042. The tracking code 0014T is being retired and the successor code is CPT code 29868 (Arthroscopy, knee, surgical, osteochondral autograft(s) meniscal transplantation (including arthrotomy for meniscal insertion, medial or lateral). Placement of this code in APC 0042 is subject to comment in response to this final rule with comment period because the code is a new code for CY 2005.

Accordingly, restructured APCs 0041 and 0042 for CY 2005, as modified based on the public comment received, are shown in Tables 1 and 2 below.

Table 1.--Reconstructed APC 0041: Level I Arthroscopy

CPT/HCPCS Code	Description
29850	Knee arthroscopy/surgery
29870	Knee arthroscopy/diagnostic
29871	Knee arthroscopy/drainage
29873	Knee arthroscopy/surgery
29874	Knee arthroscopy/surgery
29875	Knee arthroscopy/surgery
29876	Knee arthroscopy/surgery
29877	Knee arthroscopy/surgery
29879	Knee arthroscopy/surgery
29880	Knee arthroscopy/surgery
29881	Knee arthroscopy/surgery
29882	Knee arthroscopy/surgery
29883	Knee arthroscopy/surgery
29884	Knee arthroscopy/surgery
29886	Knee arthroscopy/surgery
29805	Shoulder arthroscopy/diagnostic
29819	Shoulder arthroscopy/surgery
29820	Shoulder arthroscopy/surgery
29821	Shoulder arthroscopy/surgery
29822	Shoulder arthroscopy/surgery
29823	Shoulder arthroscopy/surgery
29825	Shoulder arthroscopy/surgery
29834	Elbow arthroscopy/surgery
29835	Elbow arthroscopy/surgery
29836	Elbow arthroscopy/surgery
29837	Elbow arthroscopy/surgery
29838	Elbow arthroscopy/surgery
29840	Wrist arthroscopy
29843	Wrist arthroscopy/surgery
29844	Wrist arthroscopy/surgery
29845	Wrist arthroscopy/surgery
29846	Wrist arthroscopy/surgery
29848	Wrist arthroscopy/surgery
29891	Wrist endoscopy/surgery
29892	Ankle arthroscopy/surgery
29894	Ankle arthroscopy/surgery
29895	Ankle arthroscopy/surgery
29897	Ankle arthroscopy/surgery
29898	Ankle arthroscopy/surgery
29804	Jaw arthroscopy/surgery
29999	Arthroscopy of joint
0012T	Osteochondral knee autograft
29830	Elbow arthroscopy
29860	Hip arthroscopy, dx
29887	Knee arthroscopy/surgery

Table 2.--Reconstructed APC 0042: Level II Arthroscopy

CPT/HCPCS Code	Description
29851	Knee arthroscopy/surgery
29885	Knee arthroscopy/surgery
29888	Knee arthroscopy/surgery
29889	Knee arthroscopy/surgery
29806	Shoulder arthroscopy/surgery
29807	Shoulder arthroscopy/surgery
29824	Shoulder arthroscopy/surgery
29826	Shoulder arthroscopy/surgery
29827	Arthroscopic rotator cuff repair
29847	Wrist arthroscopy/surgery
29855	Tibial arthroscopy/surgery
29856	Tibial arthroscopy/surgery
29899	Ankle arthroscopy/surgery
29800	Jaw arthroscopy/surgery
0013T	Osteochondral knee allograft
29861	Hip arthroscopy/surgery
29862	Hip arthroscopy/surgery
29863	Hip arthroscopy/surgery
29868	Meniscal transplantation, knee

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6. Angiography and Venography Except Extremity

APC 0279: Level II Angiography and Venography Except Extremity

APC 0280: Level III Angiography and Venography Except Extremity

APC 0668: Level I Angiography and Venography Except Extremity

a. February 2004 Panel Meeting

As requested by the APC Panel, at the February 2004 Panel meeting, we presented our proposal for reconfiguring APCs 0279, 0280, and 0668 that reflected changes based on prior input with outside clinical experts. The APC Panel had previously reviewed these APCs during its January 2003 meeting and had recommended that we not restructure these three APCs until we received input from clinical experts in the field. When we updated the APC groups in CY 2003, we accepted the APC Panel's recommendation and made no changes to APCs 0279, 0280, and 0668.

A review of these APCs was prompted by a commenter who requested that we move CPT code 75978 (Repair venous blockage) from APC 0668 to APC 0280 and that we move CPT code 75774 (Artery x-ray, each vessel) from APC 0668 to APC 0279. The commenter submitted evidence in support of these requests and testified before the APC Panel regarding the common use of CPT code 75978 for treating dialysis patients and the often required multiple intraoperative attempts to succeed with this procedure for such patients.

After receiving input from the clinical experts, we determined that these three APCs should be revised to improve their clinical homogeneity. At the February 2004 meeting, we presented our proposed restructuring of APCs 0279, 0280, and 0668 to the APC Panel. The APC Panel concurred with our proposal.

In addition, subsequent to the APC Panel meeting, we discovered several procedures in these APCs that were more appropriately placed in other APCs in order to remedy any 2 times rule violations. We included those modifications in our proposed restructured APCs published in Table 3 in the August 16, 2004 proposed rule.

b. Public Comments Received

Comment: Several commenters requested that CMS postpone or cancel the proposed plans for moving angiography codes 75960 (Transcatheter introduction of intravascular stent(s), (non-coronary vessel) percutaneous and/or open, radiological supervision and interpretation, each vessel), 75962 (Transluminal balloon angioplasty, peripheral artery, radiological supervision and interpretation), 75964 (Transluminal balloon angioplasty, each additional peripheral artery, radiological supervision and interpretation), 75966 (Transluminal balloon angioplasty, renal or other visceral artery, radiological supervision and interpretation), and 75968 (Transluminal balloon angioplasty, each additional visceral artery, radiological supervision and interpretation), which are integral to a number of angioplasty and stent placement procedures, from APC 0280 to APC 0668. One commenter indicated that the proposed decreases in payments for these services that would result from their APC reassignment were inconsistent with CMS' proposal to limit payment decreases for device-dependent APCs. Another commenter was particularly concerned that code 75962, which is used for angioplasty of arterial blockages, may have a wide range of associated procedure costs. The commenters stated that aggregate payment for all services billed for many high volume procedures such as peripheral transluminal angioplasty and single stent placement will decrease by 16 to 21 percent, in large part due to the reassignment of codes 75960, 75962, 75964, 75966, and 75968 to the lower level APC 0668 in the angiography and venography except extremity series and

to their placement on the bypass list. Two commenters were concerned that supervision and interpretation services as part of peripheral atherectomy procedures were assigned to higher paying APC 0279, potentially providing hospitals with an incentive to perform atherectomy instead of angioplasty or stent procedures, or both. Further, the commenters suggested that the lower payment for the supervision and interpretation services moved to APC 0668 for CY 2005 provides an incentive for hospitals to treat patients on an inpatient basis or may limit beneficiaries' access to the outpatient procedures. One commenter indicated that the cost and complexity of performing angiographic procedures for angioplasty are similar, if not more complex, than those of performing angiographic procedures for atheretomy.

The commenters did not understand why CMS reassigned the supervision and interpretation codes from a Level III to a Level I APC and believed that CMS did not take into account the higher level of hospital resources and staffing required for certain therapeutic radiology supervision and interpretation services. Further, they questioned the assumptions CMS adopted in the creation of the bypass list to develop ''pseudo''single claims. They suggested that there might be significant differences between the multiple procedure claims that CMS converts to ''pseudo'' single claims and those that CMS is unable to use. Thus, the commenters questioned the reliability of the claims data and encouraged CMS to use external data as the basis for the decisionmaking. One commenter noted that, of a large number of claims for APC 0668, 79 percent accounted for device costs and 81 percent accounted for room charges, but CMS' single claim methodology had only 4 percent of claims accounting for device costs or room charges.

Finally, one commenter, a group of providers, stated that they expected substantial payment decreases to result from the proposed restructuring of APCs 0279, 0280, and 0668. The commenter suggested that CMS should establish a mechanism (such as dampening) to offset large payment swings similar to those anticipated as a result of the CMS proposal.

Response: Our analyses of claims data used for the CY 2004 OPPS and several past comments led us to recognize the need to restructure APCs 0279, 0280, and 0668 for the CY 2005 OPPS. There were only two services in APC 0668 for CY 2004, APC 0279 was excepted from the 2 times rule in CY 2004, and the median costs for individual services in APCs 0668, 0279, and 0280 showed significant overlap. The APC Panel also acknowledged the need to reconfigure these APCs. In our proposed rule, we presented the restructured APCs in which the procedures within each APC demonstrated both clinical and resource homogeneity, and our final data confirmed the appropriate assignment of the services. For instance, the peripheral atherectomy supervision and interpretation codes (75992 through 75996) assigned to the Level II APC (0279) consistently had higher median costs than the supervision and interpretation codes for intravascular stent placement or peripheral or visceral artery balloon angioplasty, which are assigned to the Level I APC (0668). For CY 2005, the median costs for the supervision and interpretation codes for stent placement and angioplasty were much lower than the median cost of their prior APC 0280 ($1,181) and were within the range of median costs ($239–$444) for other procedures assigned to APC 0668. As APCs 0668, 0279, and 0280 are not device-dependent APCs because we expect the devices to be reported with the interventional procedures provided (that are in device-dependent APCs), it would be inappropriate to apply the device-dependent APC policy to APCs 0668, 0279, and 0280. In addition, there were no violations of the 2 times rule in the restructured APCs 0668, 0279, or 0280 based on full year 2003 hospital claims data.

The supervision and interpretation codes 75960, 75962, 75964, 75966, and 75968, along with peripheral atherectomy supervision and interpretation CPT codes, were proposed for the bypass list for CY 2005. As the commenters noted, we recognized that angiography and venography services generally involve multiple procedure claims, and less than 10 percent of bills for APCs 0668, 0279, and 0280 were available for ratesetting for CY 2004. We proposed to place a number of radiological supervision and interpretation codes on the bypass list for CY 2005 because we believed that these codes should have little packaging associated with them and we recognized that their addition to the bypass list might enable us to use significantly more data from multiple procedure claims for APCs 0668, 0279, 0280, and others. We did not expect that devices and room charges would generally be packaged with the supervision and interpretation services, but rather would be packaged with the interventional procedures they accompanied. This accounts for the low percentage of device and room costs on the single bills in APC 0668 used for the median calculation. None of the commenters provided any information about why it would be inappropriate to include these codes on the bypass list, other than to point out the decline in proposed payment rates for the services. If packaging appropriately attributable to the supervision and interpretation services through the bypass procedure had been assigned to the interventional procedures that the supervision and interpretation services accompanied (such as angioplasty or stent placement), there should have been increases in the median costs for the interventional procedures. We did not see any such significant increases, and believe that our data do not indicate any specific packaging allocation problems with respect to the supervision and interpretation services. We have no evidence of underreporting of costs used to calculate the median costs for APC 0668.

For CY 2005, we had a significantly greater number of single claims available for use in median calculation for APCs 0668, 0279, and 0280. For example, for CY 2005, the median costs for the two supervision and interpretation codes with the highest volume that were of concern to the commenters (codes 75960 and 75962) were based on 20 percent of claims in contrast to only 1 percent used last year. While it is possible, as suggested by the commenters, that there may be differences between the packaging in multiple procedure claims that we were able to convert to ''pseudo'' single claims and those that we were unable to use, we have no reason to believe that these issues are unique to these APCs or especially problematic for these supervision and interpretation services. Our goal continues to be to use as much of our historical hospital claims data to set payment rates as possible. As we have consistently stated, we are pursuing strategies to improve our ability to utilize multiple procedure claims for median calculation, including discussions with the APC Panel Data Subcommittee.

With regard to the commenter's suggestion that we establish a mechanism to offset payment changes from one year to the next, we understand the commenter's desire for a stable system. However, while we are not convinced that an overall dampening policy is required, we continue to work toward improving the hospital claims data through education, data management, and data analyses. We believe that we have achieved significant improvements so far.

c. Final Policy for CY 2005

After consideration of the APC Panel's recommendations and the public comments we received on the August 16, 2004 proposal, we are finalizing our proposal for the restructuring of APCs 0668, 0279, and 0280.

Tables 3, 4, and 5 reflect the final restructuring of APCs 0668, 0279, and 0280.

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Table 3.—Restructured APC 0668: Level I Angiography and Venography Except Extremity

CPT/HCPCS Code	Description	CY 2004 APC	CY 2005 APC
75660	Artery x-rays, head and neck	0279	0668
75705	Artery x-rays, spine	0279	0668
75733	Artery x-rays, adrenals	0280	0668
75960	Transcatheter introduction, stent	0280	0668
75961	Retrieval, broken catheter	0280	0668
75962	Repair arterial blockage, peripheral artery	0280	0668
75964	Repair artery blockage, each	0280	0668
75966	Repair arterial blockage, renal or other visceral	0280	0668
75968	Repair arterial blockage, each		
	additional visceral	0280	0668
75970	Vascular biopsy	0280	0668
75978	Repair venous blockage	0668	0668

Table 4.—Restructured APC 0279: Level II Angiography and Venography Except Extremity

CPT/HCPCS Code	Description	CY 2004 APC	CY 2005 APC
75658	Artery x-rays, arm	0280	0279
75741	Artery x-rays, lung	0279	0279
75746	Artery x-rays, lung	0279	0279
75756	Artery x-rays, chest	0279	0279
75774	Artery x-rays, each vessel	0668	0279
75810	Vein x-ray, spleen/liver	0279	0279
75825	Vein x-ray, trunk	0279	0279
75827	Vein x-ray, chest	0279	0279
75833	Vein x-rays, kidneys	0279	0279
75887	Vein x-ray, liver	0280	0279
75891	Vein x-ray, liver	0279	0279
75992	Atherectomy, x-ray exam	0280	0279
75993	Atherectomy, x-ray exam	0280	0279
75994	Atherectomy, x-ray exam	0280	0279
75995	Atherectomy, x-ray exam	0280	0279
75996	Atherectomy, x-ray exam	0280	0279

Table 5. —Restructured APC 0280: Level III Angiography and Venography Except Extremity

CPT/HCPCS Code	Description	CY 2004 APC	CY 2005 APC
75600	Contrast x-ray exam of aorta	0280	0280
75605	Contrast x-ray exam of aorta	0280	0280
75625	Contrast x-ray exam of aorta	0280	0280
75630	X-ray aorta, leg arteries	0280	0280
75650	Artery x-rays, head and neck	0280	0280
75662	Artery x-rays, head and neck	0279	0280
75665	Artery x-rays, head and neck	0280	0280
75671	Artery x-rays, head and neck	0280	0280
75676	Artery x-rays, neck	0280	0280
75680	Artery x-rays, neck	0280	0280
75685	Artery x-rays, spine	0279	0280
75710	Artery x-rays, arm/leg	0280	0280
75716	Artery x-rays, arms/legs	0280	0280
75722	Artery x-rays, kidney	0280	0280
75724	Artery x-rays, kidneys	0280	0280
75726	Artery x-rays, abdomen	0280	0280
75731	Artery x-rays, adrenal gland	0280	0280
75736	Artery x-rays, pelvis	0280	0280
75743	Artery x-rays, lungs	0280	0280
75885	Vein x-ray, liver	0279	0280
75889	Vein x-ray, liver	0279	0280

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7. Packaged Codes in APCs

As a result of requests from the public, the Packaging Subcommittee of the APC Panel was established to review all the CPT codes with a status indicator of ''N.'' Status indicator ''N'' indicates that payment for packaged codes is bundled into the payment that providers receive for separately payable codes for items or services provided on the same day. Providers have often suggested that many codes could be billed alone, without any separately payable service on the claim, and requested that these codes not be assigned status indicator ''N.'' The Packaging Subcommittee identified areas for change of some packaged CPT codes for items or services that could be provided as the sole service on a given date. During the September 2004 meeting, the APC Panel accepted the report of the Packaging Subcommittee and made the following recommendations:

- The Panel recommended that the Packaging Subcommittee review packaged codes individually instead of making a global decision for all packaged codes.
- The Panel recommended that CMS assign a modifier to CPT codes 36540 (Collect blood venous device), 36600 (Withdrawal of arterial blood), 51701 (Insert bladder catheter), and 97602 (Wound[s] care, non-selective) to be used when these codes are the only code on that particular claim for the same date of service. The APC Panel indicated that it would revise this subset of codes once data become available.
- The Panel recommended that CMS educate providers and intermediaries on the correct billing procedures for the packaged CPT codes 36540, 36600, 51701, and 97602.
- The Panel recommended that CMS not change the status indicator for CPT 76397 (Ultrasound guidance for vascular access). The Panel indicated that it would review the data on this code as they become available.
- The Panel recommended that the Packaging Subcommittee continue to meet throughout the year to discuss other problematic packaged codes.

CMS is considering the recommendation that a modifier be used when certain codes are the only codes on a particular claim for the same date of service. We note that code 97602 is assigned a status indicator of ''A'' in this final rule with comment period, and is no longer payable under OPPS. Therefore, a modifier, if applicable, would not be assigned for this code.

Comment: One commenter asked CMS to review all the packaged codes to determine which codes should become separately payable. Several commenters also requested that codes 36540 (Collect blood venous device), 36600 (Withdrawal of arterial blood), and 97602 (Wound[s] care, nonselective) become separately payable because they are often the only procedure on a bill. In cases where there is no separately payable code on a claim, providers do not receive payment for these packaged services.

Response: We appreciate the commenters' suggestions. As stated above, the APC Panel Packaging Subcommittee recently reviewed all the packaged codes. We are currently

considering whether to create a modifier to be used for CPT codes 36540, 36600, and 51701 when these codes appear on a claim without any separately payable code on the same date of service. As stated above, code 97602 will not be payable under OPPS for CY 2005 and, therefore, is excluded from this discussion. Additional detailed suggestions for the Packaging Subcommittee should be submitted to *APCPanel@cms.hhs.gov* with ''Packaging Subcommittee'' in the subject line.

Comment: Two commenters requested that code 76937 (Ultrasound guidance for vascular access) be assigned to APC 0268 (Ultrasound Guidance Procedures), with status indicator ''S'' instead of the proposed status indicator ''N.''

Response: We are accepting the APC Panel's recommendations that code 76937 remain packaged for CY 2005. We are concerned that there will be unnecessary utilization of this procedure if it is separately payable. In addition, because code 76937 only became effective on January 1, 2004, there are currently no claims data for this code. When we review the CY 2004 claims data for the CY 2006 payment rates, we will reexamine the status of code 76937. We also note that the APC Panel Packaging Subcommittee remains active, and additional issues and new data concerning the packaging status of codes will be shared for their consideration as information becomes available.

Comment: Several commenters requested that the following CPT codes become unpackaged: 42550 (Injection for salivary x-ray) and other x-ray injection codes; 75998 (Fluoroscopic guidance for central venous access device placement); 74328 (Endoscopic catheterization of the biliary ductal system, S&I); 74329 (Endoscopic catheterization of the pancreatic ductal system, S&I); 74330 (Combined endoscopic catheterization of the biliary and pancreatic ductal systems, S&I); 36500 (Insert of catheter, vein); 75893 (venous sampling by catheter); 75989 (abscess drainage under x-ray); 76001 (Fluoroscope exam); 76003 (Needle localization by x-ray); 76005 (Fluoroguide for spine inject); 90471 and 90472 (Immunization administration); 94760, 94761, and 94762 (Pulse oximetry); and G0269 (Occlusive device in vein art). The commenters were concerned that the OPPS has denied hospitals reimbursement for these services.

Response: Hospitals include charges for packaged services on their claims, and the costs associated with these packaged services are then bundled into the costs for separately payable procedures on the claims. Hospitals may use CPT codes to report any packaged services that were performed, consistent with CPT coding guidelines. Because these imaging codes are packaged, their presence on a claim that includes a code for another separately payable service does not necessarily result in the claim being a multiprocedure claim. Payment for these imaging services is packaged in this way into payment for the separately payable services with which the imaging services are billed.

The Packaging Subcommittee reviewed every code that was packaged in CY 2004. The Committee narrowed the list of packaged codes to a list of potentially problematic codes and subsequently reviewed utilization and median cost data for these codes. One of the main criteria evaluated by the Packaging Subcommittee to determine whether a code should become unpackaged was how likely it was for the code to be billed without any other code for separately payable services on the claim. We encourage submission of clinical scenarios involving currently packaged codes to the Packaging Subcommittee for review at future meetings. Submissions should be sent to the *APCPanel@cms.hhs.gov* with ''Packaging Subcommittee'' in the subject line.

We will continue to package CPT codes 42550 and other x-ray injection codes, 75998, 73428, 74329, 74330, 36500, 75893, 75989, 76001, 76003, 76005, 90471, 94472, 94760, 94761, 94762, and G0269 for CY 2005 and will discuss these codes with the APC Panel Packaging Subcommittee.

Comment: One commenter requested that the status indicator for code G0102 (Prostate cancer screening; digital rectal examination) be changed from packaged to separately payable. The commenter indicated that the screening is administered as part of the initial preventive physical examination. The commenter stated, ''The payment for G0102 will be zero because it is identified with status indicator 'N' which means it is packaged and not paid for separately.''

Response: Currently, under the OPPS, we do not make separate payment for code G0102. Its costs are bundled into the costs of other separately payable services furnished by the hospital on the same day. For example, a digital rectal examination is usually furnished as part of an evaluation and management service, so its payment would generally be bundled into payment for the evaluation and management service when a covered evaluation and management service is furnished on the same day as the digital rectal examination. It is a relatively quick and simple procedure. Likewise, when the examination is performed during the same visit as the initial preventive examination, we would expect that costs associated with the examination would be bundled into the costs for the initial preventive examination. Accordingly, we are continuing to package code G0102.

Comment: One commenter requested that we map code G0168 (Wound closure by adhesive) to an APC instead of assigning status indicator ''N'' to the code. The commenter was concerned that access to wound adhesives would be reduced if this code is not separately payable.

Response: Wound adhesives are considered supplies used to repair lacerations and surgical incisions. These products are used instead of sutures to close wounds. We do not make separate payments for sutures under the OPPS. Providers are paid when they use wound adhesives in the same manner as they are paid for other ''packaged'' procedures. The charges for code G0168 should be packaged into whichever procedure(s) is billed on the same date of service. Payment to the provider reflects the cost of performing the procedure and the related supplies.

C. Limits on Variations Within APCs: Application of the 2 Times Rule

Section 1833(t)(2) of the Act provides that the items and services within an APC group cannot be considered comparable with respect to the use of resources if the median (or mean) of the highest cost item or service within an APC group is more than 2 times greater than the median of the lowest cost item or service within that same group. However, the statute authorizes the Secretary to make exceptions to this limit on the variation of costs within each APC group in unusual cases such as low volume items and services. No exception may be made in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act. We implemented this statutory provision in § 419.31 of the regulations. Under this regulation, we elected to use the highest median cost and lowest median cost to determine comparability.

During the APC Panel's February 2004 meeting, we presented data and information concerning a number of APCs that violate the 2 times rule and asked the APC Panel for its recommendation. We discuss below the APC Panel's recommendations specific to each of these APCs, our proposals in

response to the APC Panel's recommendations that were discussed in the August 2004 proposed rule, and our final policies.

1. Cardiac and Ambulatory Blood Pressure Monitoring

APC 0097: Cardiac and Ambulatory Blood Pressure Monitoring

We expressed concern to the APC Panel that APC 0097 appears to violate the 2 times rule. We sought the APC Panel's recommendation on revising the APC to address the violation. Based on clinical homogeneity considerations, the APC Panel recommended that we not restructure APC 0097 for CY 2005.

We proposed to accept the APC Panel's recommendation that we make no changes to APC 0097 for CY 2005. We did not receive any public comments on our proposal. Accordingly, in this final rule, we are not making any changes to APC 0097 for CY 2005.

2. Electrocardiograms

APC 0099: Electrocardiograms

We expressed concern to the APC Panel at its February 2004 meeting that APC 0099 appears to violate the 2 times rule. We asked the APC Panel to recommend options for resolving this violation. Based on clinical homogeneity considerations, the APC Panel recommended that we not alter the structure of APC 0099 for CY 2005.

We proposed to accept the APC Panel's recommendation that we make no changes to APC 0099 for CY 2005. We did not receive any public comments on our proposal. Accordingly, in this final rule with comment period, we are not making any changes to APC 0099 for CY 2005.

3. Excision/Biopsy

APC 0019: Level I Excision/Biopsy

APC 0020: Level II Excision/Biopsy

APC 0021: Level III Excision/Biopsy

We expressed concern to the APC Panel at its February 2004 meeting that APC 0019 appears to violate the 2 times rule. We advised the APC Panel that this violation was not evident in CY 2004 because the CY 2002 median cost data used in calculating the CY 2004 APC updates supported moving CPT codes 11404 (Removal of skin lesion) and 11623 (Removal of skin lesion) from APC 0020 and APC 0021. However, based on the CY 2003 data reviewed by the APC Panel, APC 0019 would violate the 2 times rule. Therefore, we asked the APC Panel to recommend an approach to resolve the violation. We asked the APC Panel if we should leave this APC as is; divide APC 0019 into two separate APCs; or move some codes in APC 0019 to higher level excision/biopsy APCs. In making its recommendation, the APC Panel noted that the 2 times violation in APC 0019 was minor, and recommended that we not modify APC 0019.

We proposed to accept the APC Panel's recommendation to not make any modifications to APC 0019 for CY 2005. We did not receive any public comments on our proposal. Accordingly, in this final rule with comment period, we are not making any changes to APC 0019 for CY 2005.

4. Posterior Segment Eye Procedures

APC 0235: Level I Posterior Segment Eye Procedures

We expressed concern to the APC Panel at its February 2004 meeting that APC 0235 appears to violate the 2 times rule. At the August 2003 APC Panel meeting, the APC Panel recommended that we monitor the data for APC 0235 for review at its February 2004 meeting. In order to address the apparent violation, we asked the APC Panel to consider moving a few CPT codes from APC 0235 into a higher level posterior segment eye procedure APC. The APC Panel noted that the 2 times violation in APC 0235 was minor, and recommended that we not change APC 0235.

We proposed to accept the APC Panel's recommendation that we make no changes to the structure of APC 0235 for CY 2005. We receive one public comment regarding this proposal.

Comment: One commenter urged CMS not to finalize the proposal to keep the CY 2004 structure of APC 0235 for CY 2005. The commenter asked CMS to consider moving codes 67220 (Treatment of choroids lesion), 67221 (Ocular photodynamic therapy), 67225 (Eye photodynamic therapy, add-on), 67101 (Repair detached retina), and 67141 (Treatment of retina) to a higher level Posterior Segment Eye Procedure APC.

Response: After further analysis, we continue to believe that the resources and clinical characteristics of these codes are most compatible and homogeneous with those services in Level I Posterior Segment Eye Procedures, APC 0235. We plan to discuss the possible restructuring of APCs 0235, 0236, and 0237 (Level I, Level II, and Level III Posterior Segment Eye Procedures, respectively) at the next APC Panel meeting. We invite comments on these APCs.

In this final rule with comment period, we are adopting as final the proposal not to make any changes to APC 0235 for CY 2005.

5. Laparoscopy

APC 0130: Level I Laparoscopy

APC 0131: Level II Laparoscopy

We expressed concern to the APC Panel at its February 2004 meeting that APC 0130 appears to violate the 2 times rule. We suggested moving CPT code 44970 (Laparoscopy, appendectomy) from APC 0130 to APC 0131. The APC Panel recommended that we make this change.

We proposed to accept the APC Panel's recommendation to move CPT code 44970 from APC 0130 to APC 0131. We did not receive any public comments on our proposal. Accordingly, in this final rule with comment period, we are adopting as final without modification our proposal to move CPT code 44970 from APC 0130 to APC 0131.

6. Anal/Rectal Procedures

APC 0148: Level I Anal/Rectal Procedure

APC 0155: Level II Anal/Rectal Procedure

APC 0149: Level III Anal/Rectal Procedure

APC 0150: Level IV Anal/Rectal Procedure

We expressed concern to the APC Panel at its February 2004 meeting that APC 0148 appears to violate the 2 times rule. We suggested moving CPT code 46020 (Placement of seton) from APC 0148 to a higher level anal/rectal procedure APC. The APC Panel reviewed the four anal/rectal APCs (APC 0148, 0149, 0150, and 0155) and recommended moving CPT codes 46020 and 46706 (Repair of anal fistula with glue) from APC 0148 to APC 0150. The APC Panel also recommended moving CPT codes 45005 (Drainage of rectal abscess) and 45020 (Drainage of rectal abscess) from APC 0148 to APC 0155.

We proposed to accept the APC Panel's recommendations specific to APC 0148. We received one favorable public comment on our proposal. Accordingly, in this final rule with comment period, we are adopting as final without modification our proposal and are moving CPT codes from APC 0148 to APCs 0150 and 0155 as shown in the Table 6 below.

Table 6.—Movement of Anal/Rectal Procedures from APC 0148 to APC 0150 and APC 0155

CPT/HCPCS	Description	CY 2004 APC	CY 2005 APC
46020	Placement of seton	0148	0150
46706	Repair anal fistula with glue	0148	0150
45005	Drainage of rectal abscess	0148	0155
45020	Drainage of rectal abscess	0148	0155

7. Nerve Injections

APC 0204: Level I Nerve Injections

APC 0206: Level II Nerve Injections

APC 0207: Level III Nerve Injections

APC 0203: Level IV Nerve Injections

We expressed concern to the APC Panel that APC 0203 and APC 0207 appear to violate the 2 times rule. After careful consideration of new data presented during the February 2004 meeting, the APC Panel recommended moving CPTs 64420 (Nerve block injection, intercostal nerve), 64630 (Injection treatment of nerve), 64640 (Injection treatment of nerve), and 62280 (Treatment of a spinal cord lesion) from APC 0207 to APC 0206. The APC Panel also recommended moving CPT code 62282 (Treatment of a spinal canal lesion) from APC 0207 to APC 0203.

After reviewing more recent, complete calendar year data that was not available in February 2004, we proposed to accept only the APC Panel's recommendation to move CPTs 64630 and 64640 from APC 0207 to APC 0206 and to make some other changes that we believed were appropriate to improve the nerve injection APCs' clinical and resource homogeneity, as shown in Tables 7, 8, and 9 of the proposed rule.

We received two comments regarding our proposed reassignment of four CPT codes from APC 0203 to APC 0207 to address an apparent violation of the 2 times rule.

Comment: Commenters urged CMS not to finalize the proposed changes to CPT codes 64620 (Injection treatment of nerve), 64680 (Injection treatment of nerve), 62263 (Lysis epidural adhesions) and 62264 (Epidural lysis on single day), which we proposed to move from APC 0203 to APC 0207. The commenters stated that the proposed payment for these services was well below the cost of the resources required to provide the services at an acceptable standard of care. The commenters requested that we not move these four codes from APC 0203.

Response: After further analysis, we agree with the commenters that CPT codes 64620, 62263, and 62264 should remain in APC 0203 based on clinical and resource homogeneity with the services in APC 0203. Therefore, in this final rule with comment period, we are not moving these three codes from APC 0203, as displayed in Table 9B below.

However, based on our final CY 2003 hospital data for CPT code 64680, utilizing over half of the several hundred total bills for this service for calculation of median hospital costs, we continue to believe that the resources and clinical characteristics of destruction of the celiac plexus by neurolytic nerve agent are most compatible and homogeneous with those services in Level III Nerve Injections, APC 0207. Therefore, in this final rule with comment period, we are adopting as final the proposed movement of CPT code 64680 from APC 0203 to APC 0207, as displayed in Table 9B below.

Accordingly, all of the final APC reassignments of nerve injections codes in this final rule with comment period are displayed below in Tables 7, 8, 9A, and 9B.

Table 7.—Movement of Level III: Nerve Injections CPT Codes from APC 0207 to APC 0204 and APC 0206

CPT/HCPCS	Description	CY 2004 APC	CY 2005 APC
64420	Nerve block injection, intercostal nerve	0207	0204
64421	Nerve block injection, intercostals, multiple	0207	0206
64472	Injection paravertebral cervical/thoracic, add-on	0207	0206
64476	Injection paravertebral lumbosacral, add-on	0207	0206
64630	Injection treatment of nerve	0207	0206
64640	Injection treatment of nerve	0207	0206

Table 8.—Movement of Level I: Nerve Injections CPT Codes from APC 0204 to APC 0206

CPT/HCPCS	Description	CY 2004 APC	CY 2005 APC
61791	Treatment of a trigeminal tract	0204	0206
64410	Nerve block injection, phrenic	0204	0206
64412	Nerve block injection, spinal accessory	0204	0206
64446	Nerve block injection, sciatic, continuous infusion	0204	0206
G0260	Injection for sacroiliac joint anesthesia	0204	0206

Table 9A.—Movement of Level II: Nerve Injections CPT Codes from APC 0206 to APC 0204 and APC 0207

CPT/HCPCS	Description	CY 2004 APC	CY 2005 APC
62270	Spinal fluid tap, diagnostic	0206	0204
62272	Drainage of cerebrospinal fluid	0206	0204
62310	Injection of spine cervical/thoracic	0206	0207
62311	Injection of spine lumbar/sacral (cd)	0206	0207
62318	Injection of spine with catheter, cervical/thoracic	0206	0207
62319	Injection of spine with catheter Lumbar/sacral (cd)	0206	0207

Table 9B.—Movement of Level III and Level IV Nerve Injections CPT Codes Between APC 0203 and APC 0207

CPT/HCPCS	Description	CY 2004 APC	CY 2005 Proposed APC	CY 2005 Final APC
62263	Lysis epidural adhesions	0203	0207	0203
62264	Epidural lysis on single day	0203	0207	0203
64620	Injection treatment of nerve	0203	0207	0203
64680	Injection treatment of nerve	0203	0207	0207

8. Anterior Segment Eye Procedures

APC 0232: Level I Anterior Segment Eye Procedures

APC 0233: Level II Anterior Segment Eye Procedures

We expressed concern to the APC Panel at its February 2004 meeting that APC 0233 appears to violate the 2 times rule. We suggested moving CPT codes 65286 (Repair of eye wound), 66030 (Injection treatment of eye), and 66625 (Removal of iris) from APC 0233 to APC 0232. The APC Panel agreed and recommended that we move CPT codes 65286, 66030, and 66625 from APC 0233 to APC 0232.

We proposed to accept the APC Panel's recommendation and to reassign these three codes. We received one public comment on our proposal.

Comment: One commenter asserted that the costs for performing the procedures under CPT codes 65286 and 66625 are similar to the costs for performing procedures in APC 0233 and requested that these codes not be moved to APC 0232.

Response: After further analysis, we continue to believe that the resources and clinical characteristics of codes 62586 and 66625 are most compatible and homogeneous with those services in Level I Anterior Segment Eye Procedures, APC 0232.

Therefore, in this final rule with comment period, we are adopting as final without modification our proposal and are moving CPT codes 65286, 66030, and 66625 from APC 0233 to APC 0232 as shown in the Table 10 below.

Table 10.--Reassignment of Anterior Segment Eye Procedures Codes From APC 0233 to APC 0232

CPT/HCPCS	Description	CY 2004 APC	CY 2005 APC
65286	Repair of eye wound	0233	0232
66030	Injection treatment of eye	0233	0232
66625	Removal of iris	0233	0232

9. Pathology

APC 0343: Level II Pathology

APC 0344: Level III Pathology

We expressed concern to the APC Panel at its February 2004 meeting that APC 0343 appears to violate the 2 times rule. We suggested moving CPT code 88346 (Immunoflourescent study) from APC 0343 to APC 0344. The APC Panel concurred with our proposal.

We proposed to accept the APC Panel's recommendation and to move CPT code 88346 from APC 0343 to APC 0344. We received one public comment on our proposal.

Comment: One commenter requested that CMS split APC 0344 into two APCs to create another level for the pathology procedures. The commenter stated that creation of another level would lead to more economically homogenous APCs to provide payment that more closely covers the costs of the procedures. The commenter pointed out that APC 0344, as currently configured, violates the 2 times rule and recommended that CMS split APC 0344 into two APCs and that CMS should assign them to a newly created APC rather than finalize its proposal to assign the new computer-assisted image analysis procedures to APC 0344.

Response: We believe that our proposed reassignment of CPT code 88346 from APC 0343 to 0344, as recommended by the APC Panel, will improve the resource and clinical homogeneity of the APCs. We are reluctant to make further reassignments without hospital cost data to support changes. Several of the codes that the commenter is concerned about, including APC codes 88360 (Morphometric analysis, tumor immunohistochemistry, quantitative or semiquantitative, each antibody; manual), 88368 (Morphometric analysis, in situ hybridization, each probe; manual), and 88367 (Morphometric analysis, in situ hybridization, each probe; using computer assisted technology) were new in CY 2004 and CY 2005 and, as such, we do not have available claims data for analysis.

Given the new codes mentioned by the commenter and the 2 times rule violations in APC 0342 and 0344, we expect that we will want to solicit the advice of the APC Panel regarding the configuration of all the pathology APCs: 0342, 0343, 0344, and 0661, at their next meeting. We will reexamine the APCs for future updates to the OPPS, but will not make other changes to the APCs at this time.

In this final rule with comment period, we are adopting as final without modification our proposal and are moving CPT code 88346 from APC 0343 to APC 0344.

10. Immunizations

APC 0355: Level III Immunizations (for CY 2005: Level I Immunizations)

APC 0356: Level IV Immunizations (for CY 2005: Level II Immunizations)

We expressed concern to the APC Panel at its February meeting that APCs 0355 and 0356 appear to violate the 2 times rule. In order to eliminate this violation, we suggested moving CPT 90636 (Hepatitis A/Hepatitis B vaccine, adult dose, intramuscular use) from APC 0355 to APC 0356. We also suggested moving CPT codes 90375 (Rabies immune globulin, intramuscular or subcutaneous), 90740 (Hepatitis B vaccine, dialysis or immunosuppressed patient, intramuscular), 90723 (Diphtheria-pertussis-tetanus, Hepatitis B, Polio vaccine, intramuscular), and 90693 (Typhoid vaccine, AKD, subcutaneous) from APC 0356 to APC 0355.

The APC Panel recommended moving CPT 90636 from APC 0355 to APC 0356 and CPT codes 90740, 90723, and 90693 from APC 0356 to APC 0355. The APC Panel delayed making a recommendation on CPT 90375 and requested that we collect additional cost data on this procedure for discussion at the next scheduled APC Panel meeting.

In the August 16, 2004 proposed rule, we proposed to accept the APC Panel's recommended changes to move CPT code 90740 from APC 0356 to 0355, and to move CPT code 90636 from 0355 to 0356. Based on our review of more recent claims data than were available to the APC Panel, we also determined that the medians for CPT codes 90693 and 90375 are below the $50 drug packaging threshold. Therefore, we also proposed to package both CPT codes 90693 and 90375 and to change the status indicator for CPT code 90723 to ''E'' because it is not payable by Medicare.

We received one public comment relating to CPT code 90740.

Comment: One commenter requested that CMS not reassign CPT code 90740 Recombivax 40mcg/mL (a brand name for Hepatitis B vaccine), from APC 0356 (Level II Immunizations) to APC 0355 (Level I Immunizations), as proposed. The commenter stated that the CMS median cost of $5.55 is erroneous and that the lowest published price for Recombivax 40mcg/mL in the Federal Supply Schedule is $79.33. Therefore, the commenter believed that code 90740 does not violate the 2 times rule when assigned to APC 0356.

Response: We are using the CY 2003 hospital claims as the basis for payment and we believe we have adequate claims on which to base payment for CPT code 90740 for CY 2005. We were able to use 99 percent of the claims for CPT code 90740 for median calculation and believe that our assignment of CPT code 90740 for CY 2005 is appropriate.

In this final rule with comment period, we are adopting as final without modification our proposal and are moving CPT code 90740 from APC 0356 to APC 0355 and CPT code 90636 from APC 0355 to APC 0356, as shown in Table 11, and packaging both CPT codes 90693 and 90375.

Table 11.—Movement of Immunization CPT Codes Between APC 0355 and APC 0356

CPT/HCPCS	Description	CY 2004 APC	CY 2005 APC
90636	Hepatitis A/Hepatitis B vaccine, adult dose, intramuscular use	0355	0356
90740	Hepatitis B vaccine, dialysis or immunosuppressed patient	0356	0355

11. Pulmonary Tests

APC 0367: Level I Pulmonary Tests

APC 0368: Level II Pulmonary Tests

APC 0369: Level III Pulmonary Tests

We expressed concern to the APC Panel at its February 2004 meeting that APC 0369 appears to violate the 2 times rule. We suggested moving CPT code 94015 (Patient recorded spirometry) from APC 0369 to APC 0367. The APC Panel concurred with our proposal.

In the August 16, 2004 proposed rule, we proposed to accept the APC Panel's recommendation and to move CPT code 94015 from APC 0369 to APC 0367. In addition, during our analysis of more recent claims data following the APC Panel meeting, we noted that APC 0367 violated the 2 times rule. Therefore, we proposed to reassign CPT codes 94375, 94750, 94450, 94014, 94690, and 93740 to APC 0368.

We did not receive any public comments on our proposal. Accordingly, in this final rule with comment period, we are adopting as final without modification our proposal and are moving CPT code 94015 from APC 0369 to APC 0367 and reassigning CPT codes 93740, 94014, 94375, 94450, 94690, and 94750 to APC 0368, as shown in Table 12A.

Table 12A.—Reassignment of Certain CPT Codes Among APCs 0367, 0368 and 0369

HCPCS	Description	CY 2004 APC	CY 2005 APC
93740	Temperature gradient studies	0367	0368
94014	Patient recorded spirometry	0367	0368
94015	Patient recorded spirometry	0369	0367
94375	Respiratory flow volume loop	0367	0368
94450	Hypoxia response curve	0367	0368
94690	Exhaled air analysis	0367	0368
94750	Pulmonary compliance study	0367	0368

12. Clinic Visits

APC 0600: Low Level Clinic Visits

We expressed concern to the APC Panel at its February 2004 meeting that APC 0600 appears to violate the 2 times rule. We suggested moving HCPS code G0264 (Assessment other than CHF, chest pain, asthma) to a higher level clinic visit. The APC Panel recommended that we not make any changes to APC 0600.

We proposed to accept this recommendation and not make any changes to APC 0600 for CY 2005. We received one public comment on our proposal from a provider group.

Comment: One comment recommended that CMS investigate further the apparent two times violation in APC 0600. The commenter believed that, although the APC Panel did not recommend reassignment of HCPCS code G0264 (Initial nursing assessment of patient directly admitted to observation with diagnosis other than CHF, chest pain or asthma or patient directly admitted to observation with diagnosis of CHF, chest pain or asthma when the observation stay does not qualify for G0244), in order to remedy the apparent violation, CMS should make the reassignment of G0264 to a much higher level clinic visit (APC 0602, High Level Clinic Visit) due to the resources involved in directly admitting a patient to observation. The commenter provided examples of services that the commenter believed are part of the initial observation nursing assessment provided by a hospital, including patient registration, comprehensive nursing clinical admission assessment, initiation of physician orders, coordination and scheduling of ancillary services, administration of medications, and assessment of discharge planning needs.

Response: We do not agree with the commenter's assertion that the services coded using G0264 are necessarily more resource intensive than a low-level clinic visit. The beneficiary whose observation stay would be coded using G0264 presents to the hospital following a physician visit. The beneficiary has already been assessed by the physician who, as a result of the assessment, has decided that observation care is warranted. We are concerned that hospitals may be attributing costs to the initial nursing assessment that are more appropriately attributable to observation services themselves, such as administration of medications, scheduling of tests to be conducted during the period of observation, and discharge planning. It is not apparent why the services provided in the hospital associated with admission to observation care (including some of those listed by the commenter) should require the resources of a High Level Clinic Visit (APC 0602) as the commenter suggested. Thus, we agree with the APC Panel's recommendation to leave G0264 in APC 0600.

Accordingly, in this final rule with comment period, we are adopting as final our proposal not to make any changes to APC 0600 for CY 2005.

13. Other APC Assignment Issues

We received a number of comments about specific APC assignments and payment amounts that were generated by our proposed rates or proposed changes to HCPCS code APC assignments resulting from our revisions to address violations of the 2 times rule. Those changes were not all specifically discussed in the proposed rule, but were open to comment. We respond to these comments in this section of the final rule.

a. Catheters for Brachytherapy Services

Comment: One commenter asked that CMS consider carefully in which APCs to place new CPT codes 19296, 19297, and 19298 (for placement of catheters into the breast for brachytherapy) because the services have, heretofore, been coded under unlisted code 19499, which is assigned to APC 0028 (Level I Breast Surgery) and with a proposed payment amount of $1,081 for CY 2005. The commenter believed that this

proposed amount is too low to appropriately reflect the costs of these services.

Response: We have assigned new CPT codes 19296 and 19298 in New Technology APC 1524 (New Technology-Level XIV ($3,000–$3,500)) with a payment amount of $3,250 and CPT code 19297 in APC 1523 (New Technology-Level XXIII ($2,500–$3,000)) with a payment amount of $2,750 for CY 2005 OPPS. These are new codes and the APC assignments were not included in the proposed rule. Therefore, the APC assignments are subject to comment.

b. Peripherally Inserted Central Catheters (PICC)

We received one comment regarding our proposed APC reassignment of CPT codes 36568 (Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump; under 5 years of age) and 36569 (Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump; age 5 years or older to APC 0187 (Miscellaneous placement/repositioning). We made the proposal based on a recommendation by the APC Panel during its February 2004 meeting.

Comment: One commenter requested that we not reassign CPT codes 36568 and 36569 from APC 0032 to APC 0187 as proposed.

Response: We proposed to reassign the PICC lines to APC 0187 based on our agreement with the APC Panel that there are significant differences in the clinical complexity and resource use associated with the procedures assigned to APC 0032 compared to PICC line insertion. We will reevaluate the APC assignment of the PICC line insertion once we have sufficient data to evaluate the assignment.

c. External Fixation Devices

Comment: One commenter indicated that APC 0046 (Open/Percutaneous Treatment Fracture) contains violations of the two times rules and should be broken into multiple APCs so that CPT codes 20690 (Apply bone fixation device) and 20692 (Apply bone fixation device), which are for application of external fixation devices, could be paid appropriate amounts. Other commenters asked that CMS require that claims for these codes must contain codes for the devices and asked that we revise the definition of C1713 (Anchor/screw for opposing bone to bone or soft tissue to bone (implantable)) to also apply to external fixation devices and to remove the requirement that the device be implantable. One commenter also asked that we instruct providers to bill code 20690 or 20692 when external fixation is provided with the reduction of a fracture and asked that we create a new APC to contain CPT codes 20690 and 20692.

Response: CPT codes 20690 and 20692 are currently in APC 0050 and no changes were proposed for 2005 OPPS. There are no 2 times violations in the APC in which they are located and each of these codes represents approximately one percent of the volume in the APC. Therefore we see no reason to create a new APC for these codes. The CPT codes for treatment of a fracture often include with or without fixation in the definition of the code. Where fixation is included in the definition of the code, it would be miscoding to also report 20690 or 20692; these codes should be reported if, and only if, fixation is not included in the definition of the CPT code for treatment of the fracture. Providers should review the CPT instructions and look to the AMA's guidance on coding if they have questions about when these codes should be reported.

d. Apheresis

Comment: Two commenters disagreed with our proposed reassignment of CPT code 36515 (Apheresis, adsorp/reinfuse) to APC 0111 (Blood Product Exchange) and recommended that the code be reassigned to APC 0112 (Apheresis, Photopheresis and Plasmapheresis). One of the commenters, a medical specialty society, indicated that the procedure involves an expensive disposable supply item that costs more than the proposed payment rate for APC 0111. In addition, this commenter stated that the proposed payment rate would be significantly less than the physician's office payment, which the commenter concluded indicated that the charge data used to establish the median cost of the procedure may be incorrect.

Response: APC assignments are based on clinical homogeneity and comparable resource utilization for all CPT and HCPCS codes within an APC. After careful review, we disagree with the commenters that CPT code 36515 should be reassigned to APC 0112. We believe that the resources required for CPT code 36515 are more similar to the other CPT codes in APC 0111. Thus, for CY 2005, we are adopting as final our proposal to assign CPT code 36515 to APC 0111, effective January 1, 2005.

e. Imaging for Intravenous Cholangiogram (IVC) Filter Placement and Breast Biopsy

Comment: One commenter requested that we move CPT code 75940 (Percutaneous placement of IVC filter, radiological supervision and interpretation) from APC 0187 (Miscellaneous Placement/Repositioning) to APC 0280 (Level III Angiography and Venography Except Extremity) and CPT code 76095 (Stereotactic localization guidance for breast biopsy or needle placement, each lesion, radiological supervision and interpretation) from APC 0187 (Miscellaneous Placement/Repositioning) to APC 0289 (Needle Localization for Breast Biopsy). The commenter believed that imaging for IVC filter placement and breast biopsy are entirely unrelated services to the central venous access surgical procedures comprising the majority of the codes in APC 0187.

Response: We understand the commenter's concern regarding the clinical inconsistency between the services described by CPT codes 75940 and 76095, which are assigned to APC 0187, and the central venous access (CVA) procedures that are also assigned to APC 0187. However, we disagree with the commenter's recommendation that CPT codes 75940 and 76095 be reassigned. First, if we were to accept the commenter's recommendation to reassign CPT code 75940 to APC 0280 and CPT code 76095 to APC 0289, the resource homogeneity of those two APCs would be compromised, and we would be significantly overpaying CPT code 75940 and underpaying CPT code 76095 based on the median costs of those two codes relative to the median costs of the procedures currently assigned to APCs 0280 and 0289, respectively. Further, we lack data for a number of the CVA codes in APC 0187 because they are new codes that were established in CY 2004. We believe that these new CVA codes are clinically similar to the codes that comprise APC 0187, and we estimate that they are also similar in terms of resource costs, which is why we assigned them to APC 0187. Once we have accumulated data for these new codes, we will review the configuration of APC 0187, and make whatever changes are appropriate in future updates. Therefore, we are maintaining CPT codes 75940 and 76095 in APC 0187 for CY 2005.

f. Hysteroscopic Endometrial Ablation Procedures

Comment: Some commenters opposed the APC Panel recommendation that both CPT codes 0009T (Endometrial cryoablation) and 58563 (Hysteroscopic endometrial ablation) be assigned to APC 0387 (Level II Hysteroscopy) in CY 2005. The commenters were concerned that adding endometrial cryoablation

(CPT 0009T) to APC 0387 would seriously weaken the clinical homogeneity of APC 0387 because CPT 0009T (Endometrial ablation with ultrasonic guidance) does not use hysteroscopy, and it requires an ultrasound machine and a separate capital unit, or compressor console, to provide cryotherapeutic energy. Instead, the commenters urged CMS not to keep CPT code 58563 in APC 0387, but rather, to assign it to APC 0202, in addition to assigning code 0009T to APC 0202, as we had proposed. One commenter argued that the clinical homogeneity of APC 0202 would be enhanced by grouping the two endometrial ablation procedures that use visualization to monitor and confirm the destruction of the endometrium in the same APC. Moreover, moving both CPT codes 58563 and 0009T to APC 0202 would highlight APC 0202's clinical homogeneity as a more device-intensive family of new technology procedures while better organizing APC 0387 as the group of non-device hysteroscopic procedures involving surgical removal or resection of intrauterine tissue for reasons other than abnormal uterine bleeding (AUB). The same commenter also believed that assigning both codes to APC 0202 would negate any inappropriate incentives to use either treatment because of payment. Other commenters asked that CMS create a new APC for endometrial cryoablation and place that APC on the device-dependent list as it did for cryoablation of the prostate because they have found that the device is 70 percent of the total cost of endometrial cryoablation. The commenters asked that the new APC be paid at least $3,448 to appropriately reflect the hospital's cost of the service.

Response: After careful consideration of the comments, we have decided to make final for CY 2005 our proposal to retain hysteroscopic endometrial ablation (CPT code 58563) in APC 0387. In addition, we are making final for CY 2005 our proposal to assign endometrial cryoablation with ultrasonic guidance to APC 0202. (We note that CPT code 0009T for endometrial cryoablation with ultrasonic guidance is replaced by new CPT code 58356 for CY 2005.). We believe that the need for a hysteroscope to perform hysteroscopic endometrial ablation makes it similar to the other services in APC 0387. On the other hand, Endometrial cryoablation uses a device but not a hysteroscope and, therefore, is more clinically compatible with APC 0202, which contains other resource intensive gynecologic services that also use a device but not a hysteroscope. Moreover, APC 0202 is a device-dependent APC and, therefore, a more appropriate placement for a procedure that uses a device.

g. Hysteroscopic Female Sterilization

Comment: One commenter indicated that the AMA intended create a new CPT level III tracking code for hysteroscopic female sterilization for CY 2005 and urged CMS to assign it to APC 0202. The commenter indicated that this new service places implants through a hysteroscope to occlude the fallopian tubes and that, therefore, it should be assigned to APC 0202, which would provide appropriate payment for this new service for which the implants cost $1,000 to $1,500.

Response: This service is represented by new CPT code 58565 (Hysteroscopic fallopian tube cannulation and micro insert placement), which was created after the issuance of the proposed rule. We are placing this new code to APC 0202 for CY 2005 for the OPPS. The placements of new codes in APCs, such as this code, are subject to comment during the comment period of this final rule with comment period.

h. Urinary Bladder Residual Study

Comment: One commenter asked us to keep CPT code 78730 (Urinary bladder residual study) in APC 0404 (Renal and Genitourinary Studies Level I) instead of moving it to APC 0340 (Minor Ancillary Procedures). The commenter noted that this code is being misused to report other than urinary bladder residual imaging.

Response: CPT code 78730 was created and originally valued for the Medicare Physician Fee Schedule as a procedure that required the services of a nuclear medicine technician. Subsequently, the use of the code has changed so that it is now used primarily by urologists. We do not believe that urologists perform services requiring nuclear medicine technicians and so, as the commenter pointed out, it appears that the code may now be utilized for coding a service that is different from that for which it was created.

However, we are not reassigning the code at this time, as requested by the commenter, pending further review. To that end, we would appreciate submission of resource data from other physician specialties that use CPT code 78730 for us to review in the context of our hospital data so that we can examine this issue further.

i. Intracranial Studies, Electrodiagnostic Testing, Autonomic Testing, and EEG

We received one comment relating to the APC assignments for several electrodiagnostic testing, autonomic testing, and EEG codes.

Comment: One commenter requested that CPT code 93888 (Intracranial study) be moved from APC 0266 (Level II Diagnostic Ultrasound Except Vascular) and assigned to APC 0267 (Level III Diagnostic Ultrasound Except Vascular) as it was in CY 2002; that CPT codes 95870 (Muscle test, nonparaspinal), 95900 (Motor nerve conduction test), and 95904 (Sensory NCV) be assigned to APC 0218 (Level II Nerve Muscle Tests); that CPT codes 95921, 95922, and 95923 (Autonomic nerve function tests) be assigned to APC 216 (Level III Nerve and Muscle Tests); and that CPT codes 95953 and 95956 (EEG monitoring) be assigned to APC 209 (Extended EEG Studies and Sleep Studies, Level II).

Response: Based on our final CY 2003 hospital data for CPT codes 93888, 95870, 95900, 95904, 95921, and 95922, we continue to believe that the resources and clinical characteristics of those codes are most compatible with other services in the APCs to which they are assigned. We made no proposal to change any of those APC assignments. Therefore, in this final rule with comment period, we are finalizing our continued placement of CPT code 93888 in APC 0266; CPT codes 95870, 95900, and 95904 in APC 0215; and CPT codes 95921 and 95922 in APC 0218. We are moving CPT code 95923 from APC 0215 to APC 0218 because the resources for this code are most compatible and homogenous with those services in Level II Nerve and Muscle Tests.

Based on our further review of CPT codes 95953 and 95956, we are moving these two CPT codes, as well as code 95950, to APC 0209 (Extended EEG Studies and Sleep Studies, Level II). Based on our review of clinical and resource use characteristics of these CPT codes, we discovered that 95953, 95956 and 95950 all are more homogenous with procedures assigned to APC 0209 than in their current APCs. Although we did not propose to make these reassignments in the proposed rule, based in part on the comment received and our further review, we are making these reassignments in this final rule with comment period in the interest of clinical and resource use homogeneity.

Accordingly, we are reassigning the CPT codes relating to intracranial studies, electrodiagnostics testing, autonomic testing, and EEG to APCs, as displayed below in Table 12B.

Table 12B.—Reassignment of CPT Codes Relating to Intracranial Studies, Electrodiagnostic Testing, Autonomic Testing, and EEG

CPT/HCPCS	Description	CY 2004 Final APC	CY 2005 Final APC
95923	Autonomic nerve function test	0215	0218
95950	Ambulatory EEG monitoring	0213	0209
95953	EEG monitoring/computer	0209	0209
95956	EEG monitoring, cable/radio	0214	0209

j. Therapeutic Radiation Treatment

Comment: Some commenters objected to the proposed movement of CPT code 77370 (Radiation physics consult) from APC 0305 (Level II Therapeutic Radiation Treatment Preparation) to APC 0304 (Level I Therapeutic Radiation Treatment Preparation), with a proposed reduction in the payment rate by 51 percent from the CY 2004 payment rate of $200.60. The commenters indicated that the current CY 2004 payment rate is already inadequate. The commenters expressed concern that the proposed payment of $98.27 would not compensate for the costs incurred to deliver this service and urged that CPT code 77370 remain in APC 0305.

Response: The median of $134.22 for CPT code 77370 was based on 95 percent of the total CY 2003 claims (33,070 single procedure claims out of 34,792 total claims). Based on these claims data, we believe that the movement of CPT code 77370 from APC 0305 (with a proposed median of $229.92) to APC 0304 (with a proposed median of $99.92) is appropriate. Therefore, we are finalizing our movement of CPT code 77370 from APC 0305 to APC 0304 for CY 2005.

k. Hyperthermia Procedures

Comment: One commenter expressed concern about the 9-percent decrease in the proposed payment rate for hyperthermia procedures (CPT codes 77600 through 77605) assigned to APC 0314 (Hyperthermic Therapies). The commenter asserted that the hospital charges do not reflect the tremendous capital costs associated with hyperthermia procedures. The commenter suspected that the questionably high utilization for these procedures may be a result of miscoding. The commenter requested that CMS consider the hyperthermia practice expense data submitted through the Practice Expense Advisory Council (PEAC) and Medicare Physician Fee Schedule (MPFS) processes. The commenter urged CMS to maintain the CY 2004 payment rates for hyperthermia through CY 2005 to allow additional time for the commenter to educate providers on the proper coding and cost reporting for hyperthermia.

Response: We believe the data do not support the commenter's concern that a high utilization for these codes is indicative of miscoding, as we do not consider 552 total claims to reflect a high utilization that gives rise to question. The payment rate for APC 0314 for CY 2005 noted in the proposed rule was set using 86 percent of the total claims (that is, 452 single procedure claims out of 522 total claims), which we consider to be sufficiently robust for ratesetting purposes. Therefore, we will not consider practice expense data submitted through the PEAC or MPFS processes.

l. Physician Blood Bank Services

Comment: One commenter asked that CMS place CPT codes 86077, 86078 and 86079 (Physician blood bank services) into an APC and make payment for them under the OPPS. The commenter indicated that the current assignment of status indicator ''A'' is assigned to HCPCS codes that are paid under another fee schedule but that these services are not paid under any other fee schedule or payment system and, therefore, the hospital is not being paid for these services. The commenter noted that the services had status indicator ''X'' for minor services and had APC assignments in the CY 2003 OPPS.

Response: We agree and have assigned these CPT codes to APC 343 with status indicator ''X.'' These services consist mainly of physician professional services, which are paid through the Medicare Physician Fee Schedule, but we expect there may also be some hospital resources utilized. We have given these codes a condition code of ''NI'' (new interim) in this interim final rule with comment because they were not paid under the OPPS in CY 2004 and because we were not able to use the data for these codes in the calculation of the median cost for APC 343.

m. Caloric Vestibular Test

Comment: One commenter requested an explanation for the proposed movement of CPT code 92543 (Caloric vestibular test) from APC 0363 (Level I Otorhinolaryngologic Function Tests) to APC 0660 (Level 2 Otohinplaryngologic Function Tests), and CPT codes 92553 (Audiometry, air and bone) and 92575 (Sensorineural acuity test) from APC 0365 (Level II Audiometry) to APC 0364 ((Level I Audiometry).

Response: We regularly review CPT codes to ensure that they are in appropriate clinical APCs, based on resource use and clinical homogeneity. Upon review, we have found that code 92543 fits more appropriately in a higher-paying APC in the same family of otorhinolaryngologic function test APCs, while codes 92553 and 92575 fit in a lower-paying APC in the same family of audiometry APCs.

n. APC 0365—Level II Audiometry

Comment: One commenter stated that the services in APC 0365 (Level II Audiometry) are not clinically homogeneous and also violate the 2 times rule, sometimes by a spread of 300 percent. The commenter asked that CMS split the APC into two APCs: one containing CPT codes 92604, 92602, 92603, 92601 and 92561 and a second new APC containing CPT codes 92577, 92579, 92582, 92557.

Response: We agree that revision of this APC would result in improved clinical homogeneity and better grouping of services with similar resources. Therefore, we are establishing a new APC 0366 (Level III Audiometry), and are placing in the new APC those

services that are specific to aural rehabilitation after cochlear implantation: CPT codes 92601, 92602, 92603, and 92604.

o. Noncoronary Intravascular Ultrasound (IVUS)

Comment: One commenter requested that CMS keep CPT code 37250 (Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; initial vessel) in APC 0670 (Level II Intravascular and Intracardiac Ultrasound and Flow Reserve) and to use only those claims that capture intravascular ultrasound (IVUS) device-related costs to calculate the median cost for this procedure.

Response: We assigned CPT 37250 to APC 0416 (Level I Intravascular and Intracardiac Ultrasound and Flow Reserve) in the proposed rule. We created two levels for IVUS by creating APC 0416 in order to recognize both the clinical and resource use differences between the coronary and noncoronary vessel procedures, as well as the initial vessel and each additional vessel procedures. Prior to creation of APC 0416, all IVUS procedures, coronary and noncoronary, as well as initial vessel and each additional vessel, were assigned to APC 0670. Based on analysis of our CY 2003 hospital claims data, we concluded that the services in APC 0670 had widely varying median costs, with lower median costs for both the each additional vessel (noncoronary and coronary) and initial noncoronary vessel services in APC 0670, as compared with the initial coronary vessel IVUS. We recognized that the additional vessel services would not require a second costly device in most cases. We also noted that the initial vessel coronary IVUS code, CPT 92978, includes imaging supervision and the interpretation and report, while the initial vessel noncoronary IVUS code, CPT 37250, does not include the radiological supervision and interpretation, which is billed using another CPT code. Thus, we believe that the hospital resources utilized to perform initial vessel noncoronary and coronary IVUS are likely to be different because the service elements in the CPT codes vary. Based on this review, we believe CPT 37250, a noncoronary vessel procedure with a median cost of $361, is appropriately assigned to APC 0416 and would be significantly overpaid if assigned to APC 0670.

For CY 2005, we did not have the ''C'' coded claims to use to identify device-related costs with the level of specificity that was possible for CY 2004. However, we had significantly more claims available for CPT 37250 for ratesetting this year than for CY 2004. We believe that the data on which the assignment to APC 0416 was based were reflective of hospital claims data regarding the resources utilized for the service. As we note elsewhere in this preamble, we will be requiring the use of device codes to report all devices utilized, beginning January 1, 2005.

Accordingly, in this final rule we are finalizing the assignment of CPT 37250 to APC 0416 for CY 2005.

p. Electronic Analysis of Neurostimulator Pulse Generators

Comment: One commenter stated that the services in APC 0692 (Electronic Analysis of Neurostimulator Pulse Generators) are not clinically homogeneous and also violate the 2 times rule. The commenter asked that CMS split the APC into two APCs: one containing CPT codes 95972 and 95975, and a second new APC containing CPT codes 95970, 95971, and 95974.

Response: We recognize that there is a violation of the two times rule in APC 0692. Therefore, we are moving CPT code 95970 to APC 0218 (Level II Nerve and Muscle Tests), which places it in a clinical APC that is suitable in terms of resource use for the service and results in APC 0692 conforming to the 2 times rule.

q. Endoscopic Ultrasound Services

Comment: One commenter asked that CMS create a separate APC for endoscopic ultrasound services because the commenter believed that there are unique costs associated with them. The commenter also believed that ultrasound costs were not packaged into the median for endoscopic ultrasound services because of correct coding edits that define endoscopic ultrasound services as including ultrasound.

Response: We have no reason to believe that the costs for endoscopic ultrasound services do not contain the costs for the ultrasound component of the service. Ultrasound services are included in the definition of the endoscopy CPT codes, and the hospital would include charges for the ultrasound in the charge for endoscopy that uses ultrasound services. We believe that the current APC placement of the codes for endoscopic ultrasound services in APC 0141 (Level I Upper GI Procedures) is valid, both with regard to clinical homogeneity and resource use.

r. External Counterpulsation (ECP)

Comment: Several commenters requested that G0166 (External Counterpulsation) in APC 0678 (External Counterpulsation) be assigned status indicator ''S'' rather than ''T'' and that CMS maintain the payment rate for external counterpulsation at the CY 2004 level. The commenters asserted that external counterpulsation is a stand-alone procedure and that assigning it a status indicator ''T'' has contributed to declining and inadequate payment rates for the services. The commenters argued that the proposed payment rate for CY 2005 is not reflective of the costs of the service and that the rate should be consistent with other cardiovascular equipment trends such as echocardiography. They contended that the claims data CMS used are erroneous and pointed out that the payment rate has decreased every year since CY 2000, from $112.72 in CY 2004 to a proposed rate of $105.38 for CY 2005. The commenter also speculated that ''batching'' or ''misreporting'' of claims also may be contributing to the rate decline trend for external counterpulsation.

Response: We do not believe that the rate decrease for these procedures has anything to do with the ''T'' status indicator. The rate for external counterpulsation proposed in the August 16, 2004 proposed rule was based on virtually all (35,764) of the 37,565 hospital claims submitted and the APC is comprised of only this one procedure. We are confident that the claims data are representative of actual costs and as such, that the proposed decreased rate is appropriate.

The status indicator only affects the payment rate when external counterpulsation is billed with another procedure that has a status indicator ''T.'' There are few multiple procedure claims for this procedure in the CY 2003 claims data and, thus, only a very small effect of multiple procedure discounting was possible.

In the absence of supporting information from the commenters, it is not clear what the commenters mean by considering the batching of claims as contributing to the payment decrease. It is also not clear whether or not the commenters' belief that misreporting may be contributing to the rate decline trend for external counterpulsation is justified. However, we encourage hospitals to code accurately.

D. Exceptions to the 2 Times Rule

As discussed earlier, the Secretary is authorized to make exceptions to the 2 times limit on the variation of costs within each APC group in unusual cases such as low volume items and services.

Taking into account the APC changes that we proposed for CY 2005 based on the APC Panel recommendations discussed in section II.C. of this

preamble and the use of CY 2003 claims data to calculate the median cost of procedures classified in the APCs in the August 16, 2004 proposed rule, we discussed our review of all the APCs to determine which APCs would not meet the 2 times limit. We used the following criteria to decide whether to propose exceptions to the 2 times rule for affected APCs:

- Resource homogeneity.
- Clinical homogeneity.
- Hospital concentration.
- Frequency of service (volume).
- Opportunity for upcoding and code fragments.

For a detailed discussion of these criteria, refer to the April 7, 2000 OPPS final rule with comment period (65 FR 18457).

In the August 16, 2004 proposed rule, we proposed to exempt 54 APCs from the 2 times rule based on the criteria cited above. In cases in which a recommendation of the APC Panel appeared to result in or allow a violation of the 2 times rule, we generally accepted the APC Panel's recommendation because these recommendations were based on explicit consideration of resource use, clinical homogeneity, hospital specialization, and the quality of the data used to determine the APC payment rates that we proposed for CY 2005. The median cost for hospital outpatient services for these and all other APCs can be found at Web site: *http//www.cms.hhs.gov.*

We received one public comment on our proposal.

Comment: One commenter recommended that we use statistical methods to determine variations in the medians of services mapped to an APC. Specifically, the commenter suggested the cost data for an APC should include the standard deviation and the coefficient of variation using the geometric mean as the basis for the measure of dispersion. The commenter recommended that very few APCs be allowed to violate the 2 times rule.

Response: We appreciate the commenter's recommendations. We will consider these recommendations for future recalibrations. We do currently review the range of standard descriptive statistics for all APCs, including, but not limited to, the standard deviation and coefficient of variation. As we stated in the proposed rule, we used multiple criteria to assess whether to propose exceptions to the 2 times rule for affected APCs, including resource and clinical homogeneity, hospital concentration, frequency of services, and opportunities for upcoding and code fragments. Despite an increase in the number of clinical APCs in the OPPS over the last several years, the number of APCs excepted from the 2 times rule has remained relatively stable.

The proposed rule listed exceptions from the 2 times rule based on data from January 1, 2004 through September 30, 2004. For this final rule with comment period, we used data from January 1, 2003 through December 31, 2003. As a result of the additional data, the list of APCs that we are excepting from the 2 times rule has been updated. In this final rule with comment period, we are adopting 57 APCs as excepted from the 2 times rule, as shown in Table 13 below.

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Table 13.--APCs Exceptions to the 2 Times Rule

APC	APC Description
0019	Level I Excision/ Biopsy
0024	Level I Skin Repair
0025	Level II Skin Repair
0032	Insertion of Central Venous/Arterial Catheter
0043	Closed Treatment Fracture Finger/Toe/Trunk
0046	Open/Percutaneous Treatment Fracture or Dislocation
0060	Manipulation Therapy
0080	Diagnostic Cardiac Catheterization
0081	Non-Coronary Angioplasty or Atherectomy
0087	Cardiac Electrophysiologic Recording/Mapping
0093	Vascular Reconstruction/Fistula Repair without Device
0099	Electrocardiograms
0105	Revision/Removal of Pacemakers, AICD, or Vascular
0121	Level I Tube changes and Repositioning
0122	Level II Tube changes and Repositioning
0140	Esophageal Dilation without Endoscopy
0146	Level I Sigmoidoscopy
0147	Level II Sigmoidoscopy
0148	Level I Anal/Rectal Procedure
0164	Level I Urinary and Anal Procedures
0183	Testes/Epididymis Procedures
0187	Miscellaneous Placement/Repositioning
0193	Level V Female Reproductive Proc
0203	Level IV Nerve Injections
0204	Level I Nerve Injections
0209	Extended EEG Studies and Sleep Studies, Level II
0213	Extended EEG Studies and Sleep Studies, Level I
0214	Electroencephalogram
0235	Level I Posterior Segment Eye Procedures
0236	Level II Posterior Segment Eye Procedures
0252	Level II ENT Procedures
0262	Plain Film of Teeth
0268	Ultrasound Guidance Procedures
0274	Myelography
0281	Venography of Extremity
0285	Myocardial Positron Emission Tomography (PET)
0297	Level II Therapeutic Radiologic Procedures
0303	Treatment Device Construction
0314	Hyperthermic Therapies
0322	Brief Individual Psychotherapy
0335	Magnetic Resonance Imaging, Miscellaneous
0340	Minor Ancillary Procedures
0341	Skin Tests
0342	Level I Pathology
0344	Level III Pathology
0355	Level I Immunizations
0356	Level II Immunizations
0364	Level I Audiometry
0370	Allergy Tests
0373	Neuropsychological Testing
0389	Non-imaging Nuclear Medicine
0397	Vascular Imaging
0409	Red Blood Cell Tests
0422	Level II Upper GI Procedures
0600	Low Level Clinic Visits
0688	Revision/Removal of Neurostimulator Pulse Generator Receiver
0699	Level IV Eye Tests & Treatments

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E. Coding for Stereotactic Radiosurgery Services

1. Background

In the November 7, 2003 final rule with comment period (68 FR 63403), we discussed the APC Panel's consideration of HCPCS codes G0242 (Cobalt 60-based stereotactic radiosurgery plan) and G0243 (Cobalt 60-based stereotactic radiosurgery delivery). At its August 22, 2003 meeting, the APC Panel discussed combining the coding for these procedures under one code, with the payment for the new code derived by adding together the payments for HCPCS codes G0242 and G0243. The APC Panel recommended that we solicit additional input from professional societies representing neurosurgeons, radiation oncologists, and other experts in the field before recommending changes to the coding configuration for Cobalt 60-based stereotactic radiosurgery planning and delivery.

In a correction to the November 7, 2003 final rule with comment period, issued on December 31, 2003 (68 FR 75442), we considered a commenter's request to combine HCPCS codes G0242 and G0243 into a single procedure code in order to capture the costs of this treatment in a single procedure claim because the majority of patients receive the planning and delivery of this treatment on the same day. We responded to the commenter's request by explaining that several other commenters stated that HCPCS code G0242 was being misused to code for the planning phase of linear accelerator-based stereotactic radiosurgery planning. Because the claims data for HCPCS code G0242 represent costs for linear accelerator-based stereotactic radiosurgery planning (due to misuse of the code), in addition to Cobalt 60-based stereotactic radiosurgery planning, we were uncertain of how to combine these data with HCPCS code G0243 to determine an accurate payment rate for a combined code for planning and delivery of Cobalt 60-based stereotactic radiosurgery.

In consideration of the misuse of HCPCS code G0242 and the potential for causing greater confusion by combining HCPCS codes G0242 and G0243, we created a planning code for linear accelerator-based stereotactic radiosurgery (HCPCS code G0338) to distinguish this procedure from Cobalt 60-based stereotactic radiosurgery planning. We maintained both HCPCS codes G0242 and G0243 for the planning and delivery of Cobalt 60-based stereotactic radiosurgery treatment, consistent with the use of two G-codes for planning (HCPCS code G0338) and delivery (HCPCS codes G0173, G0251, G0339, G0340, as applicable) of each type of linear accelerator-based treatment. We indicated that we intend to maintain these new codes in their current new technology APCs until the payment rates could be set using medians from this expanded set of codes. We also stated that we would solicit input from the APC Panel at its February 2004 meeting.

During the February 2004 APC Panel meeting, several presenters discussed with the APC Panel their rationale for requesting that HCPCS codes G0242 and G0243 be combined into a single procedure code. One presenter explained that the request to combine the codes was made because certain fiscal intermediaries were rejecting claims in which HCPCS codes G0242 and G0243 were reported with a surgery revenue code. Although we have not issued any national instructions to fiscal intermediaries to deny claims for these services if they are billed with a surgery revenue code, the presenter stated that we may have indirectly led some fiscal intermediaries to believe that Cobalt 60-based stereotactic radiosurgery should be reported with a radiation therapy revenue code because the procedure is separated into a planning code and a delivery code, which reflect the coding pattern of a radiation therapy procedure rather than a single code for a surgical procedure. The presenter stated that because of the way that CMS has coded this procedure, some fiscal intermediaries have established local edits to deny claims in which HCPCS codes G0242 and G0243 are reported on a claim with a surgery revenue code.

The APC Panel recommended that CMS work with the presenters to determine if any fiscal intermediaries have established local edits to reject claims in which HCPCS codes G0242 and G0243 are reported on a claim, and to determine specific reasons for any such local edits. The APC Panel also recommended that CMS take necessary action to ensure that any such claims are not being denied payment due to local edits. The APC Panel did not agree that the solution to ensuring payment was to combine HCPCS codes G0242 and G0243 into a single code, but rather recommended that CMS educate fiscal intermediaries as to the appropriate procedures for submission of these claims for Medicare payment.

2. Proposal for CY 2005

In the August 16, 2004 proposed rule, for CY 2005, we proposed to accept the APC Panel's recommendation to work with the presenters to ensure that claims in which HCPCS codes G0242 and G0243 are reported are not being inappropriately denied payment due to local edits established by fiscal intermediaries. In the meantime, for CY 2005, we proposed to maintain HCPCS code G0242 in New Technology APC 1516 (New Technology, Level XVI) at a payment rate of $1,450, and HCPCS code G0243 in New Technology APC 1528 (New Technology, Level XXVIII) at a payment rate of $5,250. These payment rates are the same as those established for CY 2004.

3. Public Comments Received and Departmental Responses

Comment: Numerous comments urged CMS to replace HCPCS codes G0242 (Cobalt 60-based multisource photon SRS, planning) and G0243 (Cobalt 60-based multisource photon SRS, delivery) with one surgical code (that is, CPT code 61793, Stereotactic radiosurgery, one or more lesions) for billing Cobalt 60-based multisource photon stereotactic radiosurgery. These commenters explained that Cobalt 60-based multisource photon SRS is considered to be a one session, neurosurgical procedure and is not separated into planning and delivery sessions. One commenter contended that this procedure is managed and performed exclusively by neurosurgeons.

In response to the OPPS final rule with comment period published on November 7, 2003, one commenter suggested that a combined surgical code representing Cobalt 60-based stereotactic radiosurgery could be appropriately assigned to APC 0222 (Implantation of Neurological Device), APC 0226 (Implantation of Drug Infusion Reservoir), or APC 0227 (Implantation of Drug Infusion Device) to reflect the device costs, the neurosurgical nature of the procedure, and the clinical homogeneity of the other CPT codes that currently reside in these APCs.

In response to the OPPS final rule with comment period published on November 7, 2003, and the OPPS proposed rule published on August 16, 2004, several commenters indicated that the current coding structure has resulted in a low volume of single procedure claims for these codes, reflecting the fact that single procedure claims are billed in error for this procedure due to the necessity of billing both HCPCS codes G0242 and G0243 to capture the planning and delivery costs of this procedure. These commenters explained that the concept of planning and delivery is representative of radiation

therapy and, therefore, does not accurately describe Cobalt 60-based multisource photon SRS. The commenters believed that the creation of HCPCS codes G0242 and G0243 has created an unnecessary burden on hospitals because commercial payors do not recognize these codes. One commenter described the burden of reporting the same service using two different coding systems as the costs associated with hiring and training additional staff, preparing individual negotiations with insurers, and addressing the rejection of claims and the delay of treatments.

In contrast, three commenters objected to the use of the term ''radiosurgery'' to describe Cobalt 60-based multisource photon SRS planning and delivery. One of these commenters indicated that Cobalt 60-based multisource photon SRS is a radiation therapy procedure. This commenter contended that the indirect costs of operating a radiation therapy department are considerably higher than that of a surgery department, when factoring in the cost of a radiation physicist and therapist. The commenter further indicated that the cost-to-charge ratio (CCR) for the radiation therapy cost center more accurately reflects the costs of providing this service relative to a surgical designation. Another commenter objected to our use of the term ''radiosurgery'' and asserted that this term is a misleading nomenclature because surgery is not involved, except for the placement of an externally attached coordinate reference frame. The commenter explained that this treatment usually consists of one or more high dose radiation treatments delivered by either a linear accelerator or a cobalt 60-based unit and, therefore, should be referred to as ''stereotactic radiation therapy.''

In response to the OPPS final rule with comment period published on November 7, 2003, one commenter urged that CMS not attempt to label stereotactic radiosurgery as either neurosurgery or external beam radiotherapy, and explained that stereotactic radiosurgery is a unique procedure that combines elements of both neurosurgery and external beam radiotherapy. This commenter recommended that we recognize CPT codes specifically designed for stereotactic radiosurgery.

Response: Considering the wide range of conflicting recommendations we received from commenters, we believe that appropriate coding for Cobalt 60-based multisource photon SRS remains a highly contentious and unsettled area of interest among hospitals, neurosurgeons, radiation oncologists, and non-Medicare payors. Based upon our reading of the comments and the observations of CMS staff, we do not believe that Cobalt 60-based multisource photon SRS can be easily classified as either a neurosurgical or radiation therapy procedure specifically. Rather, for the safe and effective delivery of Cobalt 60-based multisource photon SRS to typical patients with brain lesions, the contributions of hospital physician and nonphysician staff with expertise in neurosurgery and radiation therapy are essential for both the planning of the treatment and its delivery.

In the OPPS November 30, 2001 final rule in which we first established payment rates for stereotactic radiosurgery planning and treatment using G-codes in lieu of CPT codes, we noted that, for historical hospital claims for CPT code 61793 (Stereotactic radiosurgery), other combinations of codes from the radiation oncology CPT code section were billed most of the time as well. This confirmed our recognition of the multidisciplinary nature of the service. However, we note that the classification of stereotactic radiosurgery as either neurosurgery or radiation therapy is not relevant to payment for the service under the OPPS. Therefore, for purposes of the OPPS, we have not attributed the service to one specialty or the other.

While we consider the adoption of CPT codes that describe this service, we will continue to maintain HCPCS codes G0242 and G0243 as separate codes in their respective new technology APCs 1516 and 1528 for CY 2005. Although we recognize that the single claims data we collect from these codes may include aberrant claims due to the necessity of billing both HCPCS codes G0242 and G0243 on the same date of service for a correctly coded claim, the adoption of CPT code 61793 to replace HCPCS codes G0242 and G0243, as recommended by some commenters, would not resolve the multiple procedure claims dilemma due to the fact that typically hospitals would need to bill additional CPT codes along with CPT code 61793 to report the full range of services that are currently bundled into HCPCS codes G0242 and G0243. For example, in our November 30, 2001 final rule in which we described our determination of the total cost for stereotactic radiosurgery, to model costs for planning, we added the median costs of CPT codes 77295 (the most typical simulation code billed with CPT code 61793), 77300, 77370 (the most common physics consult billed with CPT code 61793), and 77315 (the most common dose plan billed with CPT code 61793). Furthermore, the descriptor for CPT code 61793 describes multiple forms of stereotactic radiosurgery (that is, stereotactic radiosurgery, one or more lesions; particle beam, gamma ray or linear accelerator), rather than Cobalt 60-based multisource photon SRS alone. The adoption of CPT code 61793 under the OPPS would have the effect of nullifying all of the stereotactic radiosurgery G–codes, which we are unwilling to do without cost data supporting an equal payment for all forms of stereotactic radiosurgery. In light of all the above-mentioned reasons, we believe that any stereotactic radiosurgery code changes for CY 2005 would be premature without cost data to support a code restructuring. In the meantime, we will continue to pay HCPCS codes G0242 and G0243 under their current respective new technology APCs 1516 and 1528 for CY 2005, as we continue to analyze new methods for resolving the issue of multiple procedure claims.

Comment: In response to the OPPS final rule with comment period published on November 7, 2003, and the OPPS proposed rule published on August 16, 2004, several commenters urged CMS to recognize the surgical nature of Cobalt 60-based multisource photon SRS by mapping the procedure to a surgical revenue code. The commenters claimed that some Medicare fiscal intermediaries continue to reject claims in which HCPCS codes G0242 and G0243 are reported with a surgery revenue code, and encouraged CMS to issue national instructions on the correct billing for stereotactic radiosurgery procedures. The commenters believed that revenue codes are established by the general APC in which the procedure resides. Another commenter stated that the placement of HCPCS codes G0242 and G0243 in new technology APCs labeled as radiation therapy has misled Medicare fiscal intermediaries to assume that a radiation revenue code must be reported with these claims. This commenter indicated that, as a result of providers reporting a radiation revenue code when billing HCPCS codes G0242 and G0243 and Medicare applying a radiation CCR ratio to these codes, the median costs for HCPCS codes G0242 and G0243 were understated, as the CCR for radiation is around 33 percent compared to a 45-percent to 55-percent CCR for surgery cost centers.

In response to the OPPS final rule with comment period published on November 7, 2003, and the OPPS proposed rule published on August 16, 2004, two commenters objected to the

assignment of HCPCS codes G0243 and G0173 to the same new technology APC 1528. The commenters argued that these two procedures should not be grouped into the same APC because they are clinically dissimilar and do not share the same level of resource intensity. The commenter believed that an APC grouping should be determined by the clinical nature of the procedure, its resource cost, the type of physician necessary to perform the procedure, the clinical setting in which the procedure is performed, and the clinical outcomes of the procedure. Another commenter indicated that the cost of Cobalt 60-based SRS multisource photon SRS delivery is 2.45 times the cost of linear accelerator-based SRS delivery, which the commenter believed to be an unacceptable violation of the 2 times rule. In contrast, one commenter reported that its facility has experienced no delays or claims rejections as a result of the current coding structure for stereotactic radiosurgery. The commenter urged CMS to maintain the current coding structure for Cobalt 60-based multi-source photon SRS planning and delivery, asserting that providers who carefully review the code descriptors should experience no delays or claims rejections.

Response: We believe the commenter's concerns regarding the clinical similarity and the application of the 2 times rule to a new technology APC reflect a misunderstanding of the purpose of the new technology APCS. We assign procedures to a new technology APC when we do not have adequate claims data upon which to determine the relative median cost of performing a procedure, and must rely on other sources of information (that is, external data that have been made publicly available) to determine its appropriate payment. New technology APCs do not carry clinical descriptors, such as radiation therapy; rather, the descriptor for each new technology APC represents a particular cost band (for example, $1,400 to $1,500). Payment for items assigned to a new technology APC is the mid-point of the band (for example, $1,450). As we stated in our proposed rule, we have worked together with some of the commenters to identify specific fiscal intermediaries who may be rejecting claims in which HCPCS codes G0242 and G0243 are reported. However, to date, we have been unable to identify any such local edits. Nor have we received examples of rejected claims from providers to enable us to determine why payment was not made for the claims. CMS will continue to work with providers and contractors to clarify coding and billing for all stereotactic radiosurgery procedures through program instructions, Medlearn Matters articles, and other outreach activities.

Comment: One commenter understood that the Advisory Panel on APC Groups is invested with the responsibility of providing correct coding for hospitals, and contended that the Panel should address in more detail the coding issues for stereotactic radiosurgery procedures. This commenter further indicated that the Panel is composed almost entirely of physicians rather than hospital financial personnel or hospital coders, to which the commenter objected as creating a direct conflict with hospital interests.

Response: We do not agree with the commenter's concerns regarding the Advisory Panel on APC Groups. The Panel is governed by the provisions of Pub. L. 92–463, which set forth standards for the formation and use of advisory panels (42 U.S.C. 13951 (t); section 1833(t) of the Act). According to the Charter, the function of the Panel is to review the APC groups and their associated weights and advise the Secretary of Health and Human Services and the Administrator of CMS concerning the clinical integrity of the APC groups and their weights. The subject-matter of the Panel includes to the following issues and related topics: addressing whether procedures are similar both clinically and in terms of resource use; assigning new CPT codes to APCs; reassigning codes to different APCs; and reconfiguring the APCs into new APCs. Responsibility for providing correct coding for hospitals does not fall within the purview of the Panel. Furthermore, we wish to reassure the commenter about the makeup of the Panel. The commenter's understanding that the Panel is almost entirely composed of physicians and lacks representation from hospital financial personnel or hospital coders is not accurate. As required by the Charter, all of the Panel members are currently employed in a full-time status by a hospital and serve as representatives of their hospital employer. Furthermore, only approximately half of the Panel members hold a medical degree, while the other half of the Panel members hold a hospital coding certification or nursing, pharmacy, or business degree(s), or both, or serve as hospital reimbursement officers, or both.

Comment: We received numerous comments suggesting various simplifications of the coding structure for SRS planning and delivery. Some commenters urged that CMS develop one uniform series of treatment codes for the various types of stereotactic radiation therapy, based on the process of care rather than a vendor-specific technology. One commenter suggested that CMS eliminate HCPCS codes G0338 (Linear accelerator-based SRS planning) and G0242 (Multi-source Cobalt 60-based photon SRS planning) and recognize existing CPT codes 77295 or 77301 to describe stereotactic radiation therapy planning, which the commenter believed would more accurately describe the process of care and reduce duplication in codes. Another commenter recommended that CMS eliminate HCPCS code G0242, and recognize HCPCS code G0338 for describing all forms of stereotactic radiosurgery planning by deleting the phrase that restricts the code to linear accelerator-based stereotactic radiosurgery planning.

In contrast, a commenter responding to the OPPS final rule with comment period published on November 7, 2003, suggested that CMS eliminate HCPCS code G0338, and recognize HCPCS code G0242 for all stereotactic radiosurgery planning by deleting the phrase that restricts the code to multisource Cobalt 60-based photon SRS planning. Other commenters recommended that CMS simplify the stereotactic radiosurgery delivery codes as well by eliminating HCPCS codes G0173 (SRS delivery, complete session) and G0251 (Linear accelerator-based SRS delivery, fractionated sessions), and recognizing HCPCS codes G0339 (Image guided, robotic linear accelerator-based SRS, complete or first session) and G0340 (Image guided, robotic linear accelerator-based SRS, second through fifth sessions) for all forms of stereotactic radiosurgery delivery by removing the word ''robotic'' from their descriptors. Another commenter suggested an alternative option for simplifying the stereotactic radiosurgery delivery codes by eliminating HCPCS codes G0339 and G0340, and recognizing HCPCS codes G0173 and G0251. This commenter recommended that CMS modify the descriptors for HCPCS codes G0173 and G0251 by deleting the linear accelerator specification so the codes apply to all forms of stereotactic radiosurgery delivery and deleting the maximum number of five sessions per course of treatment from the descriptor of HCPCS code G0251. One commenter suggested that CMS eliminate HCPCS codes G0173, G0251, G0339, and G0340 and recognize HCPCS code G0243 as including all stereostactic radiosurgery delivery procedures by deleting the phrase that restricts its use to

multisource Cobalt 60-based photon stereotactic radiosurgery delivery.

In response to the OPPS final rule with comment period published on November 7, 2003, one commenter indicated that HCPCS code G0340 (Image guided, robotic linear accelerator-based SRS, second through fifth sessions) should not be described by radiosurgery, contending that radiosurgery is defined by a single session treatment. The commenter recommended that the descriptor for HCPCS code G0340 be changed to ''image-guided, robotic, linear accelerator-based radiation therapy-hypofractionated delivery.'' One commenter responded to the OPPS proposed rule by applauding CMS for placing the first fraction of a multiple session treatment delivery of image-guided robotic linear accelerator-based stereotactic radiosurgery (described by HCPCS code G0339) in the same APC as a complete single session treatment delivery of image-guided robotic linear accelerator-based stereotactic radiosurgery, and stated that the resources consumed are identical, regardless of whether additional treatment sessions are delivered. This commenter agreed with CMS' placement of subsequent fractionated sessions in a lower paying APC to reflect the fewer resources consumed during the delivery of subsequent sessions.

In response to the OPPS final rule with comment period published November 7, 2003, several commenters supported CMS' decision to assign HCPCS codes G0338 (Linear accelerator-based stereotactic radiosurgery planning) and G0242 (Cobalt 60-based, multi-source photon stereotactic radiosurgery planning) to the same APC, and stated that the resource costs of both types of stereotactic radiosurgery planning are comparable. Another commenter applauded CMS' creation of HCPCS code G0338 to differentiate linear accelerator stereotactic radiosurgery planning from multisource photon stereotactic radiosurgery planning (HCPCS code G0242), due to the differences in their clinical uses and cost resources.

In response to the OPPS final rule with comment period published on November 7, 2003, one commenter supported the creation of HCPCS codes G0339 and G0340, as long as these codes are used exclusively for extracranial stereotactic radiosurgery treatments, such as those of the spine, lung, and pancreas. Due to limited cost data and clinical efficacy published on image-guided, robotic stereotactic radiosurgery used to treat extracranial indications, the commenter believed that the costs for this new and emerging technology would be more accurately captured by limiting the use of HCPCS codes G0339 and G0340 to extracranial stereotactic radiosurgery treatments.

Several commenters requested that CMS present their recommendations to the Advisory Panel on APC Groups during its next meeting in the event that the stereotactic radiosurgery code descriptors cannot be modified in time for the CY 2005 final rule.

Response: For reasons stated in a previous response, we believe that any stereotactic radiosurgery code changes for CY 2005 would be premature without cost data to support a code restructuring. For instance, in preparation of the CY 2006 OPPS Update, we intend to conduct data analysis for the first time for HCPCS codes G0338, G0339, and G0340, which were newly created G-codes for CY 2004. Therefore, until we have completed any such analysis, we will continue to maintain HCPCS codes G0173, G0251, G0338, G0339, G0242, and G0243 in their respective new technology APCs for CY 2005 as we consider the adoption of CPT codes to describe all stereotactic radiosurgery procedures for CY 2006, including the new CPT tracking codes 0082T (Stereotactic body radiation therapy, treatment delivery, one or more treatment areas, per day) and 0083T (Stereotactic body radiation therapy, treatment management, per day) that the AMA intends to make effective January 1, 2005. For CY 2005, we will assign a status indicator of ''E'' for CPT code 0082T to reflect the fact that the current G-codes for stereotactic radiosurgery treatment delivery include this service, and a status indicator of ''N'' for CPT code 0083T because we consider the treatment management per session bundled into the current stereotactic radiosurgery treatment delivery G-codes.

In reference to commenters' request that CMS present their recommendations for stereotactic radiosurgery code restructuring to the Advisory Panel on APC Groups, we refer the readers to the discussion above in an earlier response concerning the purview of the Panel's responsibilities. To the extent that the APC assignments for stereotactic radiosurgery codes are an issue, we may bring those to the attention of the Panel.

Comment: In response to the OPPS final rule with comment period published on November 7, 2003, several commenters expressed concern that the placement of HCPCS code G0340 (Image-guided robotic linear accelerator-based SRS delivery, fractionated treatment) in a higher paying new technology APC than G0251 (Non-robotic linear accelerator-based SRS delivery, fractionated treatment) creates a financial incentive to use robotic SRS technology over non-robotic stereotactic radiosurgery technology. The commenters urged that HCPCS codes G0251 and G0340 be placed in the same APC until clinical evidence supports an improved clinical outcome using robotic stereotactic radiosrugery as compared to non-robotic stereotactic radiosurgery and sound financial data supports payment differentiation. In addition to placing G0251 and G0340 in the same APC, one commenter urged that CMS remove the language ''or first session of fractionated treatment'' from the descriptor for G0339 and remove the language ''second through fifth sessions'' from the descriptor for G0340, so that placement of HCPCS codes G0251 and G0340 in the same APC will result in equal payments for the first session of fractionated therapy, regardless of the type of technology used to deliver fractionated stereotactic radiosurgery.

In response to the OPPS final rule with comment published on November 7, 2003, and the OPPS proposed rule published on August 16, 2004, several commenters asserted that the creation of HCPCS codes G0339 and G0340 was unnecessary, on the premise that all stereotactic radiosurgery and radiotherapy equipment is image guided and robotic. One commenter expressed concern that the creation of HCPCS codes G0339 and G0340, the limitation of HCPCS code G0340 to five fractionated sessions, and the placement of HCPCS code G0340 in a higher paying APC than other SRS modalities inadvertently amount to an endorsement by CMS of the CyberKnife technology. The commenter believed that the current payment rate for CyberKnife therapy results in excessive copayments for beneficiaries and unfairly advantages a technology that has provided insufficient clinical evidence of an improved outcome above existing stereotactic radiosurgery and radiotherapy modalities, and has provided CMS with no convincing cost data to support such an excessive return on investment. The commenter believed that if CMS had consulted the Medicare Coverage Advisory Committee (MCAC) or the Medical Technology Council (MTC), which advise CMS on whether specific medical treatments and technology should receive coverage, neither the MCAC nor the MTC would have recommended coverage for the CyberKnife technology. Other

commenters urged that CMS eliminate what they believe to be an unfair advantage given to HCPCS code G0339 by modifying the descriptor for HCPCS code G0173 (SRS delivery, complete session) to describe a complete session or first session of linear accelerator-based stereotactic radiosurgery delivery, and modifying the descriptor for HCPCS code G0251 to describe second through fifth sessions of linear accelerator-based stereotactic radiosurgery delivery, so that the first session of a multiple session treatment will be paid equal to that of a complete session, regardless of the type of stereotactic radiosurgery technology used.

Response: We disagree with commenters who believe that the creation of HCPCS codes G0339 and G0340, the limitation of HCPCS code G0340 to five fractionated sessions, and the placement of HCPCS code G0340 in a higher paying APC than other stereotactic radiosurgery modalities amount to an endorsement by CMS of a particular technology. We also note that the code descriptors for HCPCS codes G0339 and G0340 do not limit themselves to the CyberKnife technology. As other commenters indicated, the term ''image-guided robotic'' applies to other types of stereotactic radiosurgery besides CyberKnife. The OPPS payment system establishes payment rates for services based on relative resources utilized by hospitals to provide such services, based primarily on historical claims data if data are available. If hospital claims data are unavailable, we may consider external data to assist us. From 2000 through 2002, the manufacturer of one type of image-guided robotic stereotactic radiosurgery technology (that is, CyberKnife), along with several hospitals, provided CMS with cost data indicating the level of resources utilized in the provision of this form of stereotactic radiosurgery. We believe these data support the current placement of HCPCS codes G0339 and G0340 in their respective new technology APCs 1528 and 1525 for CY 2005.

To date, we have not received such cost data on non-robotic linear accelerator-based stereotactic radoisurgery (that is, on HCPCS codes G0173 and G0251) to aid us in determining if the current payment differentiation is appropriate. Therefore, we will maintain HCPCS codes G0339 and G0340 in APCs 1528 and 1525, respectively, and make no changes to their descriptors for CY 2005. In reference to CMS consulting a medical technology council for advice on new technology coverage, we refer the readers to section II.F.4.,''Public Comments Received Relating to Other New Technology APC Issues,'' of this final rule with comment period for a discussion of the recently established Council on Technology and Innovation.

Comment: A number of commenters, mostly providers of radiation oncology centers or departments, pointed out that stereoscopic kV x-ray guidance using infrared and/or camera technology is a new and important technology that allows for improved precision in radiation therapy targeting. These commenters indicated that kV x-ray guidance is not described by any current HCPCS or CPT code and requested that CMS create a new HCPCS G-code for payment under the OPPS. In addition, one commenter requested that CMS establish a new HCPCS code necessary for target localization in conjunction with intensity modulated radiation therapy, stereotactic radiotherapy, and stereotactic radiosurgery.

Response: The kV x-ray guidance using infrared technology came to our attention by means of an application to be considered for assignment to a new technology APC. We have recently concluded that the kV x-ray guidance should receive a temporary ''C'' code for OPPS payment under certain circumstances described below, and that it should be placed into a new technology APC. Therefore, we are creating the following HCPCS code to describe kV x-ray guidance using infrared technology:

HCPCS code C9722 (Stereoscopic kV x-ray imaging with infrared tracking for localization of target volume)

We are assigning the new HCPCS code C9722 to New Technology APC 1502 at a payment of $75, effective on January 1, 2005.

While we are assigning a C-code and payment for hospital costs, we are not assigning a G-code because we believe that the interested party should seek a CPT code from the AMA. We believe that the CPT Editorial Panel needs to assess the need for a code for the service, and, if a code is granted, evaluate the resources necessary to provide this service. This technology has been available for more than 2 years. We consider this time period to be sufficient for the interested party to request a CPT code from the AMA.

In addition, in our definition and payment instructions for this service, we are limiting additional payment for this service to occasions when kV x-ray is not billed with stereotactic radiosurgery delivery G-codes. As all stereotactic radiosurgery delivery services require guidance, the current payments for the stereotactic radiosurgery delivery G-codes (HCPCS codes G0173, G0243, G0251, G0339, and G0340) bundle payment for guidance services with stereotactic radiosurgery delivery.

4. Final Policy for CY 2005

We are adopting our proposal to maintain HCPCS codes G0173, G0242, G0243, G0251, G0338, and G0339 in their respective new technology APCs for CY 2005. We will consider the adoption of CPT codes to describe all stereotactic radiosurgery procedures in the future.

F. Movement of Procedures From New Technology APCs to Clinically Appropriate APCs

1. Background

In the November 30, 2001 final rule (66 FR 59903), we made final our proposal to change the period of time during which a service may be paid under a new technology APC. Beginning in CY 2002, we retained services within new technology APC groups until we acquired adequate data to enable us to assign the service to a clinically appropriate APC. This policy allows us to move a service from a new technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a new technology APC for more than 3 years if sufficient data upon which to base a decision for reassignment have not been collected.

In the November 7, 2003 final rule with comment period, we implemented a comprehensive restructuring of the new technology APCs to make the payment levels more consistent (68 FR 63416). We established payment levels in $50, $100, and $500 intervals and expanded the number of new technology payment levels.

2. APC Panel Review and Recommendation

During the APC Panel's February 2004 meeting, the APC Panel heard testimony from several interested parties who requested specific modifications to the APCs for the radiation oncology APC. They asked the APC Panel to make several recommendations: (1) That we move CPT code 77418 (Radiation treatment delivery, Intensity-modulated radiation therapy (IMRT)) from APC 0412 (IMR Treatment Delivery) back into a new technology APC; (2) that we dampen, or limit, any possible payment reductions to APC 0301 (Level II Radiation Therapy); (3) that we accept more external data to evaluate costs; and (4) that we identify more claims that are useful for ratesetting.

In response to the testimony presented, the APC Panel recommended that we reassign CPT code 77418 to the new technology APC 1510 for CY 2005 and that we explain to providers any steps we take to limit payment reductions to APC 0301 so that they can better plan for future years during which we may decide not to apply a dampening, or payment reduction limitation, to the rates for APC 0301.

In the August 16, 2004 proposed rule, we did not propose to accept the APC Panel's recommendations because we believe that we have ample claims data for use in determining an appropriate APC payment rate for CPT code 77418. Moreover, we believe that the development of median cost for CPT code 77418 based on those data is representative of hospital bills.

We have over 255,000 claims for this service, and over 95 percent were single claims that we could use for ratesetting. Moreover, the APC medians have been stable for the last 2 years of data. As indicated by our claims data, returning code 77418 to new technology APC 1510 would result in a payment for the service that is significantly higher than the resources utilized to provide it.

We refer the readers to section II.F.4., ''Public Comments Received Relating to Other New Technology APC Issues,'' of this final rule with comment period for a discussion of the public comments and our final policy regarding the APC placement of CPT code 77418 for CY 2005.

Comment: Several commenters objected to the proposed assignment of CPT code 77418 to APC 0412 at a payment rate of $307.78. These commenters disagreed with CMS' conclusion that the significant volume of single claims used to set the payment rate accurately reflects the costs hospitals incur to provide this service, and argued that hospitals are inaccurately coding this service and submitting insufficient charges for delivering this therapy. One commenter raised concerns that some providers are incorrectly billing procedures other than IMRT under CPT code 77418. Commenters urged CMS to accept the recommendation of the Advisory Panel on APC Groups to return CPT code 77418 to a new technology APC with a payment rate comparable to the CY 2003 payment rate of $400.

Response: As we noted previously, we do not accept the Panel's recommendation to move CPT code 77418 back to a new technology APC. We believe the 2 years (that is, CYs 2002 and 2003) that CPT code 77418 was in new technology APC 0710 allowed ample opportunity for providers to receive proper instruction on correctly coding and billing for this service. The proposed payment rate of $307.78 for CY 2005 was set using 96 percent of the total claims (that is, 246,045 single procedure claims out of 255,020 total claims) for CPT code 77418, which deeply supports its current placement in clinical APC 0412. Therefore, we will maintain CPT code 77418 in APC 0412 for CY 2005.

Comment: Several commenters objected to the proposed movement of CPT code 77301 (Radiotherapy dose plan, IMRT) from new technology APC 1510 (New Technology, Level X) with a payment rate of $850 to clinical APC 0310 (Radiation treatment preparation, Level III) with a payment rate of $811.91. The commenters indicated that this procedure is relatively new and that hospitals appear to be inaccurately reporting the costs of providing this service. The commenters recommended that, until more data can be collected and analyzed, CMS retain CPT code 77301 in new technology APC 1510 at a payment rate of $850.

Response: We move a procedure from a new technology APC to a clinical APC when we have adequate claims data for ratesetting. We believe that the proposed movement of CPT code 77301 from new technology APC 1510 to clinical APC 0310 is appropriate, considering that 88 percent of the total claims (66,076 single procedure claims out of 74,911 total claims) were used to set the payment rate of $811.91 for APC 0301. Furthermore, CPT code 77301 has been placed in a new technology APC for the past 3 years (that is, CY 2002 through CY 2004), which we believe to be ample time for providers to receive proper instruction on correctly coding and billing for CPT code 77301. Therefore, as proposed, we are moving CPT code 77301 from new technology APC 1510 to clinical APC 0310 for CY 2005.

Comment: One commenter requested that new CPT 0073T (Compensator-based beam modulation treatment delivery of inverse planned treatment using three or more high resolution (milled or cast) compensator convergent beam modulated fields, per treatment session) be assigned to APC 0412 with an ''S'' status indicator. The commenter believed that the assignment of 0073T should be the same as that for CPT 77418.

Response: We agree with the commenter and are assigning CPT 0073T to APC 0412 with status indicator ''S'' for CY 2005.

3. Proposed and Final Policy for CY 2005

There are 24 procedures currently assigned to new technology APCs for which we have data adequate to support assignment into clinical APCs. Therefore, in the August 16, 2004 proposed rule, we proposed to reassign these procedures to clinically appropriate APCs. We proposed to assign 24 of the procedures that were listed in Table 14 of the proposed rule to clinically appropriate APCs using CY 2003 claims data to set medians on which payments would be based.

As we did in the proposed rule, we present below a further explanation to provide a fuller understanding of the payment rates for several of the procedures that we proposed to move out of new technology APCs and into clinical APCs.

a. Photodynamic Therapy of the Skin

For CPT code 96567 (Photodynamic therapy of the skin), the impact of the payment decrease between CY 2004 and CY 2005 is actually low, as the CY 2004 payment included the topically applied drug required to perform this procedure and the CY 2005 payment does not. We will now pay separately for the drug billed under HCPCS code J7308 in CY 2005. We have adequate claims data on which to base payment for that procedure in a clinically appropriate APC. Payment based on those data in addition to removal of the drug for separate payment resulted in a lower median cost for the APC.

Comment: Several commenters objected to the proposed movement of CPT code 96567 (Photodynamic therapy of the skin) from New Technology APC 1540 (New Technology, Level III) with a payment rate of $150 to clinical APC 0013 (Level II Debridement and Destruction) with a proposed payment rate of $66.15. The commenters recognized that the drug (that is, HCPCS code J7308) used with this procedure is no longer bundled into the payment for CPT code 96567, and agreed that some payment reduction is appropriate. However, the commenters indicated that the proposed payment rate for APC 0013 would not cover the costs of providing this service even after excluding the costs of the drug.

Response: We believe that the resources and the clinical nature of CPT code 96567 are consistent with other codes that are placed in APC 0013. Therefore, in this final rule with comment period, we are finalizing our proposal to move CPT code 96567 from New Technology APC 1540 to clinical APC 0013 for CY 2005.

Comment: One commenter brought to our attention that CPT code 96571 (Photodynamic therapy, additional 15 minutes) may have been moved mistakenly from New Technology APC 1541 to clinical APC 0012 (Level I Debridement and Destruction). The commenter suggested that CPT code 96571 be placed in the same clinical APC 0013 (Level II Debridement and Destruction) as CPT code 96570 (Photodynamic therapy, 30 minutes).

Response: We agree with the commenter that CPT code 96571 was mistakenly moved to APC 0012 in the proposed rule. Because CPT code 96571 is an add-on code for an additional 15 minutes of photodynamic therapy, reported in addition to CPT code 96570, which describes the first 30 minutes of therapy, we believe that both codes, with status indicator ''T,'' should be placed in APC 0015 (Level III Debridement and Destruction). Therefore, in this final rule with comment period, we are moving CPT code 96571 from New Technology APC 1541 to clinical APC 0015 for CY 2005.

b. Left Ventricular Pacing, Lead and Connection

Based on a comparison of payment rates for CY 2004 and CY 2005, it appears that there is a large increase in payment that results from reassigning CPT code 33224 (Insertion of left ventricular pacing, lead and connection) from its new technology APC to a clinical APC. The difference is due to the fact that the CY 2005 APC payment includes the cost of the left ventricular lead that was not included in the CY 2004 new technology APC payment. The left ventricular lead was paid as a pass-through device under HCPCS code C1900 in CY 2004, but is not eligible for pass-through payments in CY 2005, and, as such, is now included in the APC for the procedure.

Similarly, the CY 2005 payment rate for CPT code 33225 (Left ventricular pacing lead add-on) includes the cost of the ventricular lead. However, for code 33225, the data are still somewhat unstable. Therefore, in the proposed rule, we maintained CPT code 33225 in a new technology APC, but at a higher payment level, to reflect the additional cost of the lead.

We received no comments and, therefore, we are reassigning CPT code 33224 to a clinical APC for CY 2005.

c. Positron Emission Tomography (PET) Scans

PET–FDG (Nonmyocardial)

In the proposed rule, we noted that a number of positron emission tomography (PET) scans currently are classified into APC 1516. We recognized that PET is an important technology in many instances and want to ensure that the technology remains available to Medicare beneficiaries when medically necessary. We believe that we have sufficient data to assign PET scans to a clinically appropriate APC. However, we have been told that if the effect of doing so is to reduce payment significantly for the procedure, it may hinder access to this technology. Therefore, as indicated in the August 16, 2004 proposed rule, we considered three options as the proposed payment for these procedures in CY 2005, based on our review of the 2003 claims data for the PET procedures. We specifically invited comments on each of these options.

Option 1: Continue in CY 2005 the current assignment of the scans to New Technology APC 1516 prior to assigning to a clinical APC.

Option 2: Assign the PET scans to a clinically appropriate APC priced according to the median cost of the scans based on CY 2003 claims data. Under this option, we would assign PET scans to APC 0420 (PET Imaging).

Option 3: Transition assignment to a clinical APC in CY 2006 by setting payment in CY 2005 based on a transition payment of a 50–50 blend of the median cost and a New Technology APC payment for CY 2004. We would assign the scans to New Technology APC 1513 for the blended transition payment.

We included the proposed rates for these options in Addendum B of the proposed rule.

Comment: Many commenters supported maintaining a number of PET scans in New Technology APC 1516 for CY 2005, as presented under option 1 of the proposed rule. These commenters expressed concern that options 2 and 3 set forth in the proposed rule would greatly impede patient access to PET technology. They stated that options 2 and 3 fail to account for the significant degree of variation in hospital mark-up practices and capital depreciation methods associated with PET procedures and, therefore, underestimate hospitals' costs for performing PET scans. These commenters further explained that the majority of hospitals report PET procedures under an overall diagnostic radiology revenue code rather than distinguishing PET procedures under a diagnostic nuclear medicine revenue code. The commenters expressed concern that PET claims data, when adjusted using a cost to charge ratio not specific to PET, underestimate the relative costs associated with PET imaging procedures.

Another commenter commissioned a time-and-motion study at nine PET facilities in geographically diverse regions of the United States to estimate hospitals' actual costs for providing PET scans. According to the commenter, this cost study concluded that many hospitals could not afford to provide PET scans at a payment rate below $1,450. In addition, the commenter indicated that the cost study suggested that hospitals need to perform three or more scans per day in order to break even at the current payment rate of $1,450 per scan. The commenter pointed out that using a marketing share-weighted average, the cost study found that PET facilities across the United States are performing an average of 2.63 PET scans per day, translating into a loss of $165.18 per scan for most PET providers at the current payment rate of $1,450 per scan. However, the commenter did not clarify whether this national average of performing 2.63 PET scans per day reflects utilization by both hospitals and freestanding PET centers. The commenter urged that PET remain in new technology APC 1516 for CY 2005, and noted that any reductions in payment, including the proposed blended payment rate of $1,150, would significantly impede patient access to this technology, especially in rural settings where the volume of PET scans tends to be lower. Another commenter that provides FDG to 300 PET imaging centers in geographically diverse regions of the United States reviewed their May, June, and July 2004 data for these PET centers and reported an average number of 1.88 PET scans provided per day and a median of 1.3 PET scans provided per day across the 300 PET centers. Again, the commenter did not clarify whether this national average of performing 1.88 PET scans per day reflects utilization by both hospitals and freestanding PET centers. This commenter expressed concern that any reduction in payment for PET scans, with or without a reduction in payment for FDG, may drive many PET centers into an operating deficit and reduce the availability of PET scans for Medicare beneficiaries.

Response: We appreciate the many comments we received on this topic and the efforts undertaken by several of the commenters to provide us with additional data concerning the costs of providing the scans. We acknowledge variations in hospital markup practices, capital depreciation and other cost allocation methods, although we note that the CCRs in the various reported cost centers (that is, Nuclear Medicine,

Imaging Department, Radiology) for PET procedures are fairly consistent. The median hospital CCR for these cost centers ranges from 0.3118 to 0.3172, and does not vary greatly from the median overall hospital CCR of 0.33. We believe that the robust number of claims (that is, 55,838 single procedure claims out of 61,492 total claims, representing 91 percent of the total claims) provides sufficient data to assign PET scans to a clinically appropriate APC. However, we received numerous comments indicating that any reduction in payment for PET scans would hinder access by Medicare beneficiaries to this technology. Based on our review of the comments, we are setting the CY 2005 payment for PET scans based on a 50–50 blend of the median cost and the CY 2004 new technology APC payment rate, as presented under option 3 in the proposed rule. PET scans will be assigned to new technology APC 1513 for a blended payment rate of $1,150 for CY 2005.

Comment: One commenter pointed out that the CY 2003 hospital claims data may not account for the current shift to PET/CT technology, which the commenter stated has virtually doubled the cost of launching a viable PET operation, from an average cost of $1,200,000 for a dedicated PET scanner to an average cost of $2,400,000 for a PET/CT scanner. The commenter estimated that approximately 90 percent of the PET systems currently being sold are PET/CT scanners and predicted that the current installed base of approximately 35 percent PET/CT and 65 percent dedicated PET will shift to an overwhelming majority of PET/CT scanners within the next 5 years. The commenter argued that investment in a PET/CT scanner is important to be competitive in the marketplace, due to better capability for detecting malignancies. The commenter stated that the higher capital costs of a PET/CT operation require a patient volume of between four and five patients per day to break even compared to a patient volume of between two and three patients for a dedicated PET operation. According to the commenter, the number of claims for PET remains relatively low compared to MRI and CT scans, comprising less than 1 percent of all imaging procedures performed in the United States. Therefore, the commenter argued that providers would be unlikely to recover significant losses through increased patient volume.

Several commenters indicated that the American Medical Association will be creating three new CPT codes 78814, 78815, and 78816 to describe PET with concurrent CT for anatomical localization for CY 2005. One commenter recommended that CMS assign these new CPT codes for PET/CT scans to three different new technology APCs, while another commenter recommended that CMS place these new CPT codes in new technology APC 1516 at a payment rate of $1,450.

Response: The current G code descriptors do not describe PET/CT scan technology, and should not be reported to reflect the costs of a PET/CT scan. At present, we have decided not to recognize the CPT codes for PET/CT scans that the AMA intends to make effective January 1, 2005, because we believe the existing codes for billing a PET scan along with an appropriate CT scan, when provided, preserve the scope of coverage intent of the PET G-codes as well as allow for the continued tracking of the utilization of PET scans for various indications. We plan to issue billing guidance through program instructions and provider education articles for hospitals to use when they provide both a PET and CT scan to patients in their outpatient department. While we acknowledge that PET/CT scanners may be more costly to purchase than dedicated PET scanners, a PET/CT scanner is versatile and may also be used to perform individual CT scans, thereby potentially expanding its use if PET/CT scan demand is limited.

Comment: One commenter supported assigning PET procedures to new technology APC 1513 at a payment rate of $1,150, based on a 50–50 blend of the median cost and the CY 2004 new technology payment, as presented under option 3 of the proposed rule. This commenter stated that option 3 provides the best balance between ensuring continued beneficiary access to this valuable technology and the need for CMS to consistently apply its ratesetting methodology to determine payment rates. Another commenter supported the assignment of PET procedures into a clinically appropriate APC that pays at least $1,200. This commenter believed that a payment of at least $1,200 would compensate adequately for the technology and necessary staffing.

Response: We agree with the commenters that a balance must be reached between ensuring continued beneficiary access to PET scans and the necessity for CMS to apply consistently its rate-setting methodology. Balancing the concern regarding possible adverse effects on patient access that might result from a substantial precipitous reduction in payment with information from thousands of hospital claims and the cost data we received from commenters, we are setting the CY 2005 payment for PET scans based on a 50–50 blend of the median cost and the CY 2004 new technology APC payment rate, as presented under option three in the proposed rule. We believe we have reached this balance for CY 2005 by assigning PET scans to new technology APC 1513 for a blended payment rate of $1,150.

Comment: Another commenter addressed the issue of three new CPT codes 78811, 78812, and 78813 for tumor PET imaging to replace CPT code 78810 (Tumor imaging, positron emission tomography, metabolic evaluation) for CY 2005. The commenter recommended that CMS adopt these new CPT codes in place of the existing G-codes and place them in new clinical APCs, which would result in one level for brain PET scans, two levels for cardiac PET scans, and three levels for tumor PET scans.

Response: At present, we believe that the existing G-codes for PET scans adequately serve the purpose of tracking utilization of PET scans for various indications. Therefore, CMS will continue to recognize the existing G-codes for PET scans.

Comment: One commenter requested that CMS provide the number of single procedure claims that support assigning FDG-PET scans to a clinically appropriate APC according to the median cost of the scans, as presented under option 2 in the proposed rule.

Response: The number of single procedure claims used to create the median of $898.64 discussed in the proposed rule under option 2 for APC 0420 (PET imaging) totaled 55,838 single procedure claims out of 61,492 total claims.

PET (Myocardial)

Comment: One commenter brought to our attention that CPT code 78459 (myocardial imaging, PET, metabolic evaluation) and HCPCS code G0230 (PET imaging; metabolic assessment for myocardial viability following inconclusive SPECT study) are both currently paid under OPPS and describe nearly the same procedure, with the exception that HCPCS code G0230 has a more narrow description. The commenter understood that CMS had intended to replace HCPCS code G0230 with CPT code 78459, but was confused by the payable status indicator for both codes. Two commenters recommended that CMS clarify the proper use of these codes and move CPT code 78459 from APC 0285 (Myocardial Positron Emission Tomography), with a payment rate of $690.61 to APC 1516 with a payment rate of $1,450.

Response: We appreciate the commenter bringing to our attention the

duplication of codes for myocardial PET imaging for metabolic assessment. At present, we will change the status indicator for CPT code 78459 (Myocardial imaging, PET, metabolic evaluation) to ''B,'' not payable under the OPPS, and move HCPCS code G0230 (PET imaging; metabolic assessment for myocardial viability following inconclusive SPECT study), along with the other PET codes currently assigned to APC 1516, from APC 1516 to APC 1513 for CY 2005. We will seek advice on the APC placement of HCPCS code G0230 from the Advisory Panel on APC Groups during their next meeting.

Comment: Several commenters indicated that the resources, other than the radiopharmaceuticals, required to perform the PET myocardial perfusion imaging studies assigned to APC 0285 (Myocardial Positron Emission Tomography) do not differ significantly from many of the PET tumor imaging procedures contained in new technology APC 1516. These commenters requested an explanation for the payment rate decrease from $1,058.87 in the proposed rule for the CY 2004 update to $772.08 in the final rule for the CY 2004 update, and the further decrease to $690.61 in the proposed rule for the CY 2005 update. The commenters objected to CMS creating an exception to the 2 times rule for APC 0285. The commenters believed that the small volume of these procedures and the complexity of multiple G-codes to describe both single and multiple imaging sessions preclude reasonable conclusions about the cost of providing these services. The commenters recommended that CMS move the 18 G-codes from APC 0285 paying $690.61 to APC 1516 with a payment rate of $1,450. The commenters further recommended that we reduce the complexity of billing for these procedures by collapsing these eighteen G-codes into two CPT codes based on resources for single and multiple studies, replacing HCPCS codes G0030–G0047 with CPT code 78491 (Myocardial imaging, PET, perfusion; single study at rest or stress) and CPT code 78492 (Myocardial imaging, PET, perfusion; multiple studies at rest or stress).

Response: The steady decline of the payment rate for APC 0285 since the CY 2004 proposed rule is attributable to the 153-percent increase in the number of single procedure claims used to set the payment rate for APC 0285, which gave rise to better data to more accurately set the payment rate. In the CY 2004 proposed rule, we used 613 single procedure claims out of 1,584 total claims (39 percent of total claims) to set the CY 2004 proposed payment rate of $1,058.87. In the CY 2004 final rule, we used 1,089 single procedure claims out of 1,778 total claims (61 percent of total claims) to set the CY 2004 final payment rate of $772.08. In the CY 2005 proposed rule, we used 1,451 single procedure claims out of 1,946 total claims (75 percent of total claims) to set the CY 2005 proposed payment rate of $690.61. At present, composition of APC 0285 will be maintained for CY 2005 while we collect claims data on HCPCS codes G0030 through G0047. Based on our CY 2003 data for the specific G-codes, we cannot identify a predictable pattern of increased hospital costs associated with multiple studies as compared with single studies. We will present before the Advisory Panel on APC Groups during their next meeting the commenters' recommendation to recognize CPT codes 78491 and 78492 as representing single and multiple myocardial PET studies and movement of these codes from APC 0285 to APC 1516. We note that we will be moving the PET scans currently in APC 1516 to APC 1513 for CY 2005, and will bring that to the Panel's attention as they consider potential APC movement of the myocardial PET studies.

d. Bard Endoscopic Suturing System

For CY 2005, we proposed to create APC 0422 for Level II Upper GI Procedures and to assign HCPCS code C9703 (the Bard Endoscopic Suturing System), as well as other procedures to APC 0422 based on clinical and resource homogeneity. Currently, HCPCS code C9703 is assigned to New Technology APC 1555, with a payment of $1,650. Our examination of CY 2003 claims data for HCPCS code C9703 revealed that 137 of the 171 single claims were from a single institution with an extremely low and consistent cost per claim. We do not believe that those 137 claims represent the service described by HCPCS code C9703, which includes an upper gastrointestinal endoscopy along with suturing of the esophagogastric junction. Therefore, in establishing the median for APC 0422, we did not use the 137 claims, which we believe were incorrectly coded.

Comment: Several commenters opposed the movement of HCPCS code C9703 (Bard Endoscopic Suturing System) from New Technology APC 1555 with a payment rate of $1,650 to clinical APC 0422 (Level II Upper GI Procedures) with a proposed payment rate of $1,274. The commenters indicated that the proposed payment under APC 0422 is inadequate to cover even the equipment costs alone. The commenters contended that the claims data are insufficient to support movement of this procedure out of its new technology APC and into a clinical APC, and urged CMS to maintain HCPCS code C9703 in New Technology APC 1555 with a payment rate of $1,650.

Response: As we stated in the proposed rule, our examination of the CY 2003 claims data for APC 0422 revealed that 137 of the 171 single claims for HCPCS code C9703 were incorrectly coded. Therefore, the remaining single claims were used in establishing the median for APC 0422. Considering that HCPCS code C9703 has remained in a new technology APC for 2 years with a relatively modest volume, we are not convinced that maintaining HCPCS code C9703 in a new technology APC will necessarily result in a high volume for future ratesetting. Furthermore, the median cost as calculated for HCPCS code C9703, using the subset of single claims, has been relatively stable over the past 2 years and consistent with the median for APC 0422. In addition, in keeping with our practice to use CPT codes, if possible, we will discontinue HCPCS code C9703 and instruct providers to report service with this technology under CPT code 0008T (Upper gastrointestinal endoscopy with suture), which will be payable under the OPPS for CY 2005. In this final rule with comment period, we are finalizing our proposal to move HCPCS code C9703, which will be replaced with CPT code 0008T, from New Technology APC 1555 to clinical APC 0422 for CY 2005. Code 0008T is assigned status indicator ''NI'' and, as such, is open for public comment during the 60-day comment period associated with this final rule with comment period.

e. Stretta System

Comment: Several commenters objected to the movement of HCPCS code C9701 (Stretta system) from New Technology APC 1557 with a payment rate of $1,850 to clinical APC 0422 (Level II Upper GI Procedures) with a proposed payment rate of $1,274. The commenters indicated that the proposed payment is inadequate to cover even the equipment costs alone, and urged CMS to maintain HCPCS code C9701 in New Technology APC 1557 with a payment rate of $1,850.

Response: The single claims volume for HCPCS code C9701 has remained modest for the past 2 years of its placement in a new technology APC. Therefore, we do not believe that maintaining HCPCS code C9701 in a new technology APC will necessarily result in a high volume for future

ratesetting. Furthermore, the median cost for HCPCS code C9701 has been stable over the past 2 years and consistent with the median for APC 0422. Moreover, we can now discontinue HCPCS code C9701 and will instruct providers to report service with this technology under CPT code 43257 (Upper gastrointestinal endoscopy with delivery of thermal energy), a new CPT code that will be payable under OPPS for CY 2005. We are finalizing our proposal to move HCPCS code C9701, which will be replaced with CPT code 43257, from New Technology APC 1557 to clinical APC 0422 for CY 2005.

f. Gastrointestinal Tract (GI) Capsule Endoscopy

Comment: Several comments opposed our proposal to move CPT code 91110 (GI Capsule Endoscopy) from New Technology APC 1508 with a payment rate of $650 to clinical APC 0141 (Level I Upper GI Procedures) with a proposed payment rate of $464.52 for CY 2005. (CPT code 91110 (Capsule Endoscopy) replaced HCPCS code G0262 in CY 2004. HCPCS code G0262 was mapped to New Technology APC 1508 in CY 2004.) The commenters explained that the cost data for CPT code 91110 are unreliable due to multiple coding changes over the last 3 years and, therefore, believed that the data should not be used to set the payment rate. The commenters indicated that the device costs are $450, and under the proposed payment rate, only $14 would be available to cover the service portion of the procedure. The commenters expressed concern that patient access to care would be hindered by moving the service into clinical APC 0141. The commenters also contended that the proposed assignment of this procedure to APC 0141 is inappropriate because none of the other services that reside in APC 0141 require a device of significant cost and the codes are not clinically homogeneous with CPT code 91110. The commenters urged CMS to maintain CPT code 91110 in New Technology APC 1508 with a payment rate of $650. One commenter suggested that CMS assign a C code to the capsule and instruct providers to bill this C-code along with HCPCS code G0262. One commenter requested that, if CMS does not maintain CPT code 91110 in new technology APC 1508, CMS consider two additional options: (1) Limiting the rate reduction for CY 2005 to 5 percent of the CY 2004 rate; or (2) assign CPT code 91110 to APC 0142 (Small Intestine Endoscopy), which the commenter stated would be a compromise because the payment of $503.20 would still ''underpay'' the hospital for the costs of providing the procedure.

Response: Generally, we do not establish C-codes for devices outside of the pass-through process, so we will not assign a C-code to the capsule. We remind providers that they should include the charges for device costs associated with this capsule within the charges reported for CPT code 91110. We agree with the commenters that CPT code 91110 may not belong in APC 0141 based on clinical homogeneity and resource consumption. We had almost 4,000 single claims, about 90 percent of all CY 2003 claims for capsule endoscopy, available for use in calculating the median cost of the service. We have confidence that our median reflects hospital resources needed to perform the service. As one commenter recommended, we believe that the resource costs and clinical nature of CPT code 91110 are more consistent with other codes that reside in APC 0142. Therefore, in this final rule with comment period, we are moving CPT code 91110 from New Technology APC 1508 to clinical APC 0142 for CY 2005, as the commenter suggested.

g. Proton Beam Therapy

Comment: Several commenters urged CMS to maintain intermediate (CPT code 77523) and complex (CPT code 77525) proton beam therapies in New Technology APC 1511 at a payment rate of $950 for CY 2005. The commenters indicated that the proposed payment rate of $678.31 for CY 2005 does not capture the significant difference in resource consumption and complexity between the simple and the intermediate/complex procedures. These commenters expressed concern that the low volume of claims submitted by only two facilities provides volatile and insufficient data for movement into the proposed clinical APC 0419 (Proton Beam Radiation Therapy) at a payment rate of $678.31. They pointed out that more than four additional centers are currently under construction or in the planning phases in response to the high demand for this technology. The commenters explained that the extraordinary capital expense of between $70–$125 million and high operating costs of a proton beam necessitate adequate payment for this service to protect the financial viability of this emerging technology. They feared that a payment reduction would halt diffusion of this technology and negatively impact patient access to this cancer treatment.

Two commenters explained that the CY 2005 proposed payment rates for CPT codes 77523 (intermediate proton beam treatment) and 77525 (complex proton beam treatment) were based on costs derived by applying CCRs from the most recent Medicare cost reports to charges reported on CY 2003 claims submitted by two hospitals, which were the only two proton therapy centers in operation in the United States at the time. The commenters further indicated that these two hospitals, from which all of the intermediate and complex proton therapies claims were derived, reported the costs and charges of proton therapy along with the costs and charges for all other radiation therapy services on the radiation therapy department line. One commenter calculated an overall radiation therapy department CCR of 0.2442 using CY 2003 data from one of these hospitals. This commenter then calculated a proton beam therapy CCR of 0.4175 by isolating the costs and charges for proton beam therapy from the costs and charges for the overall radiation therapy department. The commenter applied this proton beam therapy CCR of 0.4175 to calculate the costs based on average CY 2003 charges for intermediate and complex proton beam treatments and reported a cost of $1,105.96 for intermediate proton beam treatment and a cost of $1,216.60 for complex proton beam treatment, significantly above Medicare's proposed payment rate of $678.31 for CY 2005.

Commenters believed that this understatement of costs in the Medicare cost reports from these two hospitals is largely responsible for the inadequacy of the proposed payment rates for intermediate and complex proton beam treatments. The commenters requested that CMS apply the proton beam therapy CCR of 0.4175, based on proton beam specific cost data provided by one of these commenters, for determining the median costs of proton beam therapy. The commenters believed that the revised costs support the maintenance of CPT codes 77523 and 77525 in New Technology APC 1511 at a payment rate of $950 for CY 2005. The commenters also noted the recommendation of the Advisory Panel on APC Groups to maintain intermediate and complex proton beam therapies in New Technology APC 1511 at a payment rate of $950 for CY 2005 and urged CMS to adopt that recommendation.

Response: We will not apply the commenter's calculated CCR to determine the median costs of proton beam therapy because we are unable to replicate the commenter's proton beam therapy CCR calculation of 0.4175 by

isolating the costs and charges for proton beam therapy from the costs and charges for the overall radiation therapy department. However, having considered the concerns of numerous commenters that patient access to proton beam therapy may be impeded by a significant reduction in OPPS payment, we are setting the CY 2005 payment for CPT codes 77523 and 77525 by calculating a 50–50 blend of the median cost of $690.45 derived from 2003 claims and the CY 2004 new technology APC payment rate of $950. We will use the result of that calculation ($820) to assign intermediate and complex proton beam therapies (CPT codes 77523 and 77525) to New Technology APC 1510 for a blended payment rate of $850 for CY 2005.

After consideration of these public comments and based upon our review of the latest claims data available, we are moving the procedures listed in Table 14 from their current new technology APCs to the APCs listed, as we have adequate data on these procedures to enable us to make the necessary APC assignment.

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Table 14.--APC Reassignment of New Technology Procedures Into Clinical APCs

HCPCS	Descriptor	CY 2004 APC	CY 2005 APC	CY 2004 Payment Amount	CY 2005 Payment Amount
15860	Test for blood flow in graft	1501	0359	$ 25.00	$49.54
96003	Dynamic fine wire EMG	1503	0215	$150.00	$37.61
96000	Motion analyses, video/3D	1503	0216	$150.00	$150.20
96001	Motion test w/ft pressure measure	1503	0216	$150.00	$150.20
96002	Dynamic surface EMG	1503	0218	$150.00	$65.20
91110	GI tract capsule endoscopy	1508	0142	$650.00	$496.15
G0288	Reconstruction, CTA surgical plan	1506	0417	$450.00	$266.72
77301	Radiotherapy dose plan, IMRT	1510	0310	$850.00	$813.57
77523	Proton treatment, intermediate	1511	1510	$950.00	$850.00
77525	Proton treatment, complex	1511	1510	$950.00	$850.00
95250	Glucose monitoring, continuous	1540	0421	$150.00	$106.51
96567	Photodynamic treatment, skin	1540	0013	$150.00	$64.85
96570	Photodynamic treatment, 30 min.	1541	0015	$250.00	$98.28
96571	Photodynamic treatment, 15 min.	1541	0015	$250.00	$98.28
92973	Perc. Coronary thrombectomy	1541	0676	$250.00	$243.48
36595	Mech remov tunneled CV Cath	1541	0187	$250.00	$219.53
36596	Mech remov tunneled CV Cath	1541	0187	$250.00	$219.53
33224	Insert pacing lead and connect	1547	0418	$850.00	$4,246.04
33225	L ventricular pacing lead add-on	1550	1525	$1,150.00	$3,750.00
43257	Stretta System	1520	0422	$1,650.00	$1,264.79
47382	Perc. ablation liver tumor, rf	1557	0423	$1,850.00	$1,753.39
53853	Prostatic water thermometer	1550	0162	$1,150.00	$1,311.65
58356	Endometrial cryoablation	1557	0202	$1,850.00	$2,260.37
0008T	Bard Endoscopic Suturing Sys	1518	0422	$1,650.00	$1,264.79

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4. Public Comments Received Relating to Other New Technology APC Issues

a. Computerized Reconstruction CT of Aorta

In the August 16, 2004 proposed rule, we proposed to reassign code G0288 (Reconstruction, CTA of aorta for preoperative planning and evaluation post vascular surgery) from New Technology APC 1506 to clinical APC 0417 (Computerized Reconstruction) for CY 2005.

Comment: Several commenters expressed concern about our proposal to move G0288 from New Technology APC 1506 to clinical APC 0417. The commenter asserted that the reassignment results in a decreased payment amount from $450 to approximately $247, a rate that commenters believe is too low to cover the costs of providing the service.

The commenters suggested that CMS use external data to calculate rates rather than relying on hospital claims data, that CMS maintain G0288 in its current new technology APC assignment until hospital claims are more accurate, or that CMS go ahead with the reassignment to a clinical APC but continue to base payment on a rate that is consistent with the CY 2004 rate. One commenter provided invoices from hospitals across the country to support its assertion that our proposed payment will be to low.

One commenter also requested that CMS change the descriptor for code G0288 to read ''Three-dimensional pre-operative and post-operative computer-aided measurement planning and simulation in accordance with measurements and modeling specifications of the Society for Vascular Surgery'' in order to ensure that the code is only used for true three-dimensional preoperative and postoperative computer-aided measurement planning and simulation technologies.

Response: A predecessor C-code to G0288 had a new technology APC assignment in CY 2002, with a payment level of $625. The C-code was deleted for CY 2003, and G0288, a more general treatment planning code, was then assigned to the same new technology APC for CY 2003, with a payment of $625. For CY 2004, we proposed to move G0288 from a new technology APC to a clinical APC based on over 1,000 claims, with a median cost of $272. Based on hospital data provided by a commenter on the CY 2004 proposed rule and our conclusion that there may have been Medicare claims that understated the costs of the treatment planning software, we placed G0288 in a new technology APC with a payment of $450 for CY 2004, consistent with a 50/50 blend of our data with the analysis of a commenter. For CY 2005, we believe we have adequate claims data on which to base payment for G0288 and to reassign the service to its own clinical APC. We had almost 5,000 total claims for code C9703 (first 3 months of CY 2003 when the C-code was still in the grace period) and G0288, and over half of these were single claims available for APC median calculation. We are confident that the median cost for APC 0417 reflects hospital resource costs, and we are reassured by the consistency of our median cost data over the past several years for this service.

Accordingly, we are adopting as final our proposal to assign code G0288 to APC 0417 for CY 2005.

We are not changing the name of G0288 at this time. However, we will take the commenter's suggestion into consideration in the future if the need arises. We revised the descriptor for the code for CY 2004 to clarify that the service can be used for treatment planning prior to surgery and for postsurgical monitoring. We believe that the current G code descriptor appropriately describes the service.

b. Kyphoplasty

Comment: One commenter, a manufacturer of medical devices used to restore spinal function and treat vertebral compression fractures, suggested that CMS should place kyphoplasty, a new procedure to treat vertebral compression fractures, into New Technology APC 1535. The commenter stated that kyphoplasty is currently billed using code 22899 (Unlisted procedure of the spine). The commenter claimed that, according to our policy, because CMS received its application before June 2004, the procedure is eligible for new technology APC payments in October 2004. The commenter was surprised that it did not see a proposal to place kyphoplasty into a new technology APC in our proposed rule or in the October 2004 OPPS update. The commenter stated that using an unlisted code creates problems concerning billing and payment for hospitals.

Response: We have completed our evaluation of the new technology application for kyphoplasty and have assigned new C-codes that describe the procedure. We have assigned these codes to existing clinical APC 0051 rather than to a new technology APC. We believe that APC 0051 is appropriate for kyphoplasty in terms of clinical characteristics and resource costs. Reasonable placement into an existing APC that is appropriate in terms of clinical characteristics and resource costs is one of our criteria in deciding whether a service should be placed into a new technology APC (66 FR 59900, November 30, 2001).

Concerning the commenter's assertion that because CMS received its application before June 2004, the procedure is eligible for payment status as a new technology APC in October 2004, we remind the public that the timing of eligibility for payment, if any, is not bound to when an application is filed with CMS. As we state on the CMS Web site notice at *http://www.cms.gov,* if an application is filed by a certain date (for example, by June 1), the earliest date that such an item or service can be considered for new payment status is the following quarter (for example, October 1). This means that any additional coding and payment, if warranted, could begin later than the following quarter. Because it is important that our payment and coding systems do not impede access by Medicare beneficiaries to the best available medical care, we review all applications as quickly as possible, given the complexity of the issues and the thoroughness we believe such reviews require. The timing of completion of our evaluation of any specific application depends on such factors as the complexity of the application, the completeness of all materials submitted, whether the review team requires additional information and the amount of time before we receive additional materials and information. Of course, the service needs to be otherwise eligible for assignment to a new technology APC (or as a pass-through assignment in the case of a new device, drug, or biological).

We note that while we consider these new codes as final, the codes and the placement of the services are subject to comment within 60 days of the publication of this final rule with comment period, as stated elsewhere in this rule. Moreover, the public may comment on our placement of services to the APC Panel, which often hears comments and testimony concerning the placement of new services brought to us by interested parties.

Accordingly, the codes for kyphoplasty are:

C9718 Kyphoplasty, one vertebral body, unilateral or bilateral injection

C9719 Kyphoplasty, one vertebral body, unilateral or bilateral injection; each additional vertebral body (list separately in addition to code for primary procedure)

c. Laser Treatment of Benign Prostatic Hyperplasia (BPH)

In the August 16, 2004 proposed rule, HCPCS code C9713 (Non-contact laser vaporization of prostate, including coagulation control of intraoperative and postoperative bleeding) was assigned to New Technology APC 1525 for CY 2005. The assignment of this code to New Technology APC 1525 was a continuation of the new technology APC placement established on April 1, 2004.

Comment: One commenter, the manufacturer of medical equipment used in the treatment of benign prostatic hyperplasia (BPH) stated that its product, the GreenLight Laser, was the only technology available that uses a 532nm or ''green'' wavelength as an energy source and that CMS had assigned code C9713 in response to an application for a new technology APC assignment from Laserscope. The commenter indicated that other technologies that do not employ the same energy wavelength and the same noncontact vaporization technique should not be billed with code C9713. The commenter expressed concern that the costs of the other techniques are less than those for GreenLight Laser and thus the other techniques should not be paid under New Technology APC 1525. The commenter requested CMS to revise the descriptor of code C9713 to describe only 532nm laser technologies such as the GreenLight Laser.

Response: We acknowledge that HCPCS code C9713 was established following our review of the new technology application from Laserscope. We also agree that code C9713 may be used by hospitals to report such procedures using the Laserscope product, the GreenLight PVP, described in the application for new technology assignment. We established code C9713 based on our understanding of the information provided to us that the service may be different from other services used to treat BPH. We look forward to receiving and assessing the medical review, analysis, and evaluation of the service and technology through the usual AMA coding and payment processes. In general, we do not tailor temporary procedure codes in the ''C'' series to particular products and have not been persuaded that a redefinition of code C9713 is necessary at this time. With respect to other techniques for treatment of BPH, we would rely on the hospitals to determine which HCPCS code, whether C9713 or one of the CPT codes, most accurately describes the procedure for treatment of BPH for which they are billing. With regards to the commenter's claim that the costs of other techniques described by code C9713 are less than warranted by the New Technology APC 1525, our policy is to review the costs of services assigned to New Technology APCs each year to determine if an alternate placement in another APC is warranted. We continue to believe that placement of code C9713 in a new technology APC is appropriate for CY 2005.

d. Computerized Tomographic Angiography (CTA)

In the August 16, 2004 proposed rule, we included the APC assignment and the payment rate for computed tomographic angiography (CTA). These procedures, coded using one of several CPT codes, depending on the body region under study, involve acquisition of a CT scan with and without contrast material, as well as image post-processing. The assigned CTA CPT codes under APC 0662 had a proposed payment rate of $320.60. That proposed payment rate was slightly lower than that for a CT scan ($323.21) and significantly lower than the sum of the proposed payment for CT scan and image reconstruction, CPT code 76375 ($98), billed separately.

Comment: A number of commenters were concerned about the lower payment rates for the CTA procedures and asked CMS to review and revise the proposed payment rate.

The commenters pointed out that, prior to 2001, two codes were used to code for the procedure: one for the CT scan and another for the 3-D reconstruction. The commenters indicated that, in 2001, CPT codes were created to enable specific coding for CTA procedures, including image post-processing in the CTA codes, but those codes were still assigned to the same APC (0333) as CT procedures that did not include image reconstruction. They added that, in CY 2003, the CTA procedures were assigned to their own APC (0662). The commenters asserted that in spite of the creation of an APC specific to CTA procedures, the OPPS payment amounts have not reflected the additional costs for CTA compared to CT. They believed that the low payment rates are due to continuing confusion and conflicting information among providers concerning appropriate billing and charging practices associated with CTA procedures.

One commenter performed a number of analyses in an attempt to understand and address the apparent billing problems. In its investigation, the commenter discovered that, in 2002, only 40 percent of all hospitals that performed both CT and CTA charged more for CTA than for CT. The commenter also found in its study of hospital charge structures that there is wide variation in methods employed by hospitals and that only 29 percent of hospitals use costs to set charges.

While all commenters recommended that CMS adjust the payment rate for CTA procedures to equal that for APC 0333 plus APC 0282, one commenter recommended that we do this using the adjustment made under the Medicare Physician Fee Schedule for CY 2003 as a model. That commenter suggested that we should ignore CTA claims and instead rely on CT claims (APC 0333) plus reimbursement for image reconstruction (APC 0282) as a basis for setting the rate for CTA services.

Other alternative suggestions provided by the commenter include: use only CTA claims that are ''logical;'' change coding instructions and edits to allow CTA to be billed in addition to image reconstruction; or make an administrative adjustment to increase CTA payment.

Finally, the commenters encouraged CMS to investigate alternative methods for calculating CCRs in order to achieve more accurate costs on which to base our rates.

Response: Although we understand the commenters' points of view and appreciate the comprehensive analyses they shared with us, we cannot identify any action that would be appropriate for us to take. As the commenters are aware, we rely on hospital claims data to set payment rates and have made clear our intent to rely solely on those claims by CY 2007. If the claims data are inaccurate, especially across a broad spectrum of providers as the commenters believe is evidenced in this case, we have no way to determine which claims are more or less accurate than any others.

To implement the commenters' suggestion that we make the payment rate for CTA (APC 0662) equal to the sum of the rates for CT alone (APC 0333) plus image reconstruction (APC 0282) would require that we have accurate cost information about the cost of image reconstruction for CTA specifically and for CT alone, as utilized with CTA. This is not the case. The image reconstruction code CPT 76375 (coronal, sagittal, multiplanar, oblique, 3-dimensional and/or holographic reconstruction of computed tomography, magnetic resonance imaging, or other tomographic modality) is not limited to image reconstruction performed for CTA and may be used in any number of other procedures. Based on the available CPT codes for CTA, we

would not expect any current utilization of CPT code 76375 to be for CTA post-image processing, unless there was no appropriate CTA code to describe the body region imaged. We believe this would be rare. In addition, our current cost data for CT alone do not necessarily reflect the resources utilized for the CT portion of CTA.

We also do not believe that for the last 3 years there has been conflicting information given to providers concerning appropriate billing and charging practices associated with CTA procedures. The CPT code descriptors clearly include image post-processing for CTA procedures. In response to previous comments, we did provide a separate APC for CTA procedures beginning in CY 2003 in recognition that hospital resources might be different for CTA procedures as compared with CT procedures. From the over 100,000 claims for CTA procedures from CY 2003, we were able to use about 50 percent of the claims to determine hospitals' costs for the services. Our number of claims for CTA procedures increased significantly between CY 2002 and CY 2003. From the 2003 full year of data, we have calculated that median hospital costs for the APCs for CT and CTA services were approximately equal, at $329. Because hospitals set their own charges for services, which we then convert to costs, we see no reason why adding the costs for CT alone plus the costs for image reconstruction would necessarily provide a better estimate of costs for CTA than our analysis of our specific CTA claims.

Similarly, in order to make an adjustment akin to that made for the Medicare Physician Fee Schedule for CY 2003, we would need to have accurately coded cost data for the individual components of CTA, performed in the context of CTA, on which to base that change. We do not have that data, and the OPPS system, unlike the Medicare Physician Fee Schedule, relies upon historical hospital claims data to develop relative costs of services.

Lastly, we do not agree that we should provide coding guidance that differs from that embodied in the CPT code descriptors in this case. Our current edits that do not allow CTA to be billed in addition to image reconstruction are consistent with the CPT code descriptors for CTA procedures.

We created a separately paid, specific APC for those procedures in an attempt to provide an accurate payment for CTA. Moreover, by creating a unique APC for the procedures, we provided the means for hospitals to bill for all of the costs associated with CTA, entirely separate from their billing for CT. We cannot now assume that the claims billed for that APC are incorrect and that those billed for CT alone are correct.

We acknowledge the commenters' belief that the claims are flawed and that hospitals' divergent charge structures do not result in consistent charging for CT scans, CTAs or image reconstruction, but note that those claims comprise the data on which the OPPS relies for payment of a wide variety of hospital outpatient services. We must rely on hospitals to manage their charge structures in a manner that accurately and best reflects the services provided.

For the reasons stated above, we will not alter the payment rates for CTA, APC 0662, for CY 2005. Once again, we encourage hospitals to take all actions necessary to assure that they are billing accurately and including all resources utilized to deliver services. As discussed in detail in section III. of this preamble, we are continuing our work to refine the CCRs used for ratesetting.

e. Acoustic Heart Sound Services

Comment: Several commenters addressed the need to assign a recently created code for acoustic heart sound services for recording and computer analysis to an APC. One of the commenters indicated that the acoustic heart sound recording can be performed in the first 5 minutes of an emergency department service, together with an ECG, to enable the earliest possible detection of acute cardiac conditions. The commenter related that AMA's CPT Editorial Panel created three new Category III codes for acoustic heart sound recording that correspond to performing the procedure, physician interpretation of results, and recording and interpretation in combination. The commenter contended that one of these codes, CPT Category III code 0069T (Acoustic heart sound recording and computer analysis only) could be payable under the OPPS. The commenters noted that we did not propose an APC assignment for code 0069T in our proposed rule, and they requested an APC assignment effective January 1, 2005. One of the commenters believed that the most appropriate clinical APC to assign this code is APC 0099 (Electrocardiograms).

Response: One of the commenters, a manufacturer of the acoustic heart sound system, had previously applied for assignment of these codes to new technology APCs and we have previously evaluated the three acoustic heart sound services. We agree that only code 0069T could be payable under the OPPS. The comment that acoustic heart sound recording can be performed in the first 5 minutes of a visit by an ECG technician, together with an ECG, to enable the earliest possible detection of acute cardiac conditions, demonstrates that there are limited additional facility resources associated with the acoustic heart sound recording in conjunction with an ECG. It is also our understanding that the AMA's coding advice indicates that the acoustic heart sound services are to be used in conjunction with electrocardiography services. We believe it is worthwhile to recognize code 0069T under the OPPS to track its utilization and develop cost data. However, because the service may be performed quickly and is always accompanied by an ECG, we are assigning a packaged status to code 0069T for CY 2005. Although not separately payable under the OPPS, charges for the acoustic heart sound service will be packaged with charges for the separately payable services with which it is performed. With regards to the comment that we did not assign an APC in our proposed rule, we note that we do not recognize under the OPPS new CPT codes on a mid-year basis, even though the AMA may assign new tracking codes mid-year, as it did in this case. We assign new CPT codes on an annual basis, effective with our January 1 updates to the OPPS. Because this is a new code assignment that was not proposed in the CY 2005 proposed rule, interested parties will be able to comment on this new payment assignment in response to this final rule with comment period. This code is included in Addendum B.

f. Laparoscopic Ablation Renal Mass

Comment: Commenters asked that we move CPT code 50542 (Laparoscopic ablation renal mass) out of APC 0131 (Level II Laparoscopy) and place it in new technology APC 1574 (New Technology, Level XXXVII ($9,500–$10,000) until meaningful data can be obtained for the procedure. The commenter indicated that the procedure, including required devices, might cost approximately $10,000 because of the cost of the cryosurgery device. The commenter indicated that because they did not find any claims for this code that contained the device code for cryoablation probes (C2618), CMS should discard the data as being valid to set the weight for this code.

Response: Code 50542 represents a service that may or may not be performed with cryoablation equipment. Therefore, the absence of the device code for cryoablation probes on the

claims may be an accurate reflection of the service as it was performed. The median cost for the service appears to be appropriately placed in APC 0131 and the service is clinically coherent with other services in APC 0131. Therefore, we are retaining its placement in APC 0131 for CY 2005.

g. Intrabeam Intra-Operative Therapy

Comment. One commenter, the manufacturer of the Intrabeam Intra-Operative Therapy System, commented that this procedure, a treatment for women diagnosed with early-stage breast cancer, which is currently assigned to APC 0312 (Radioelement Applications) and is billed using CPT code 77776, is currently underpaid in APC 0312. The commenter claimed that there is no current APC mechanism to capture the cost information specific to this technology, and there are insufficient Medicare claims data at this time to make an appropriate clinical APC assignment. The commenter requested that CMS assign the Intrabeam procedure to a new technology APC. In addition, the commenter requested that CMS create two new level II HCPCS codes with the following descriptors: (1) Surgical placement and removal of intra-operative direct application x-ray source using surgical closure techniques; and (2) Administration of radiation therapy by intra-operative direct application of x-ray source.

Response. We recently received from the manufacturer of the Intrabeam Intra-Operative Radiation Therapy procedure an application for assignment of this procedure to a new technology APC. We are currently engaged in review of that application.

h. New Technology Process Issues

Comment: In response to the OPPS final rule with comment period published November 7, 2003, one commenter asserted that CMS had failed to establish an acceptable method for evaluating the costs and clinical efficacy of therapeutic medical technologies before assigning a code and New Technology APC payment under the OPPS. The commenter urged CMS to propose evaluation criteria for determining costs and clinical efficacy. In developing such criteria, the commenter encouraged CMS to require that all filings with the FDA be submitted to CMS for review and for CMS to rely heavily on the predicated device in the FDA application, require all privately held companies to provide CMS with a list of investors/owners, utilize generally accepted accounting principles, seek advice from the Medicare Coverage Advisory Committee (MCAC) or the Medical Technology Council (MTC), consider evaluation methods used by other health insurers, and consider recommendations from experts in the field. The commenter believed that if CMS had consulted the MCAC or the MTC, which advise CMS on whether specific medical treatments and technology should receive coverage, neither the MCAC nor the MTC would have recommended coverage for the CyberKnife technology, as an example.

In response to our August 16, 2004 proposed rule, one commenter, a device manufacturer, urged CMS to make changes to the pass-through and new technology application and evaluation processes to provide disclosure of applications filed with CMS and to create an opportunity for the public to comment on the disposition of proposed or final actions on applications. The commenter believed that public processes can be adopted, while retaining CMS' quarterly update capability for coding and payment.

Response: As required by section 942(a) of Pub. L. 108–173, we recently established the Council on Technology and Innovation (CTI) which brings together CMS senior leadership to better coordinate coverage, coding and payment policy to support the goal of high quality, high value care. The CTI aims to provide CMS with improved methods for developing practical information about the clinical benefits of new medical technologies to aid in achieving more efficient coverage and payment of these medical technologies. The CTI will also help identify and develop study methods for gathering reliable evidence about the risks and benefits of new and existing medical technologies that can be carried out more easily on a regular basis, such as simple protocols, registries, and other study methods.

The CTI will support CMS' efforts to develop better evidence on the safety, effectiveness, and cost of new and approved technologies to help promote their more effective use. As directed in section 942(a) of Pub. L. 108–173, the CMS Council coordinates the activities of Medicare coverage, coding, and payment for new technologies and the exchange of information on new technologies between CMS and other entities charged with making similar considerations and decisions.

G. Changes to the Inpatient List

At the APC Panel's February 2004 meeting, we advised the APC Panel of a request that we had received to move four codes for percutaneous abscess drainage 44901 (Drain append. abscess, percutaneous), 49021 (Drain abdominal abscess), 49041 (Drain percutaneous abdominal abscess), 49061 (Drain, percutaneous, retroper. abscess)) from the inpatient list and to assign them to appropriate APCs. The APC Panel also recommended that we evaluate other codes on the inpatient list for possible APC assignment and that we consider eliminating the inpatient list.

In the August 16, 2004 proposed rule, we proposed to remove the four above-cited codes and assign them to clinically appropriate APCs, as recommended by the APC Panel. We also proposed to assign code 44901 to APC 0037, code 49021 to APC 0037; code 49041 to APC 0037; and code 49061 to APC 0037. We discuss in section VII.E. of this final rule with comment period our response to the APC Panel's recommendation that we either abolish the inpatient list or evaluate it for any appropriate changes, the public comments we received on our proposal, and our responses to those public comments.

H. Assignment of ''Unlisted'' HCPCS Codes

1. Background

Some HCPCS codes are used to report services that do not have descriptors that define the exact service furnished. They are commonly called ''unlisted'' codes. The code descriptors often contain phrases such as: ''unlisted procedure,'' ''not otherwise classified,'' or ''not otherwise specified.'' The unlisted codes typically fall within a clinical or procedural category, but they lack the specificity needed to describe the resources used in the service. For example, CPT code 17999 is defined as ''Unlisted procedure, skin, mucous membrane and subcutaneous tissue.'' The unlisted codes provide a way for providers to report services for which there is no HCPCS code that specifically describes the service furnished. However, the lack of specificity in describing the service prevents us from assigning the code under the Medicare OPPS to an APC group based on clinical homogeneity and median cost.

In the August 16, 2004 proposed rule, we listed in Table 15 our proposed APC reassignments of unlisted HCPCS codes. In most cases, the unlisted codes are assigned to the lowest level, clinically appropriate APC group under the Medicare OPPS. This creates an incentive for providers to select the appropriate, specific HCPCS code to describe the service if one is available. In addition, if there is no HCPCS code that accurately describes the service, placing the unlisted code in the lowest level APC group provides an incentive

for interested parties to secure a code through the AMA's CPT process that will describe the service. Once a code that accurately describes the service is created, we can collect data on the service and place it in the correct APC based on the clinical nature of the service and its median cost.

We do not use the median cost for the unlisted codes in the establishment of the weight for the APC to which the code is assigned because, by definition of the code, we do not know what service or combination of services is reflected in the claims billed using the unlisted code.

Our review of HCPCS code assignments to APCs has revealed that there are a number of unlisted codes that are not assigned to the lowest level APC.

2. Proposed and Final Policy for CY 2005

In the August 16, 2004 proposed rule, we proposed to reassign specified unlisted HCPCS codes for CY 2005 OPPS to the lowest level APC in the clinical grouping in which the unlisted code is located. We displayed a listing of our proposed reassignment of the unlisted HCPCS codes in Table 15 of the proposed rule.

We received a number of public comments on our proposals.

Comment: Some commenters supported placing all unlisted codes in the lowest paid APC and noted that they believed that there are others, such as CPT code 43999 (Unlisted procedure stomach), which is now in APC 0141, that should be added to the list of those to be placed in the lowest APC. They recommended that CMS review the entire list of CPT codes to find others that should be moved to the lowest level APC.

Some commenters opposed placing ''unlisted'' or ''not otherwise classified'' codes in the lowest APC applicable to the category of service. They believed that it is inappropriate for CMS to develop payment policies aimed at forcing stakeholders to seek new HCPCS codes for the services being performed. They indicated that moving these codes to the lowest paying APC would decrease payment for 18 of the 20 procedures by more than 70 percent and would create a barrier to new technology. They indicated that CMS should analyze the costs associated with particular unlisted codes and assign them to APCs that appropriately reflect the cost to perform the services but in the meantime, should retain them in the existing APCs in which they are placed. One commenter urged us to follow the process that is followed for physician payment when unlisted codes are used, with fiscal intermediaries negotiating payment for the unlisted code depending on the actual service provided each time. One commenter indicated that putting the unlisted codes in the lowest level APC provides a disincentive for facilities to adopt new technology because it will not be paid adequately.

Response: We appreciate the support of the commenters who agreed with placing unlisted codes in the lowest APC for the clinical category. With respect to the comment that CPT code 43999 should be moved out of APC 0141 and should be placed in the lowest APC for gastrointestinal procedures, we have not moved it from APC 0141 because we believe that APC 0141 is the lowest APC appropriate to the clinical category of services for CPT code 43999.

We have reviewed again the proposed list of unlisted or ''not otherwise classified'' codes being moved to the lowest APC and based on that re-review have determined that we do not need to make any additional changes to that proposed list in this final rule with comment period.

By definition, ''unlisted'' or ''not otherwise classified'' codes do not describe the services being performed, and the services coded using ''unlisted'' codes vary over time as new CPT and HCPCS codes are developed. Therefore, it is impossible for any level of analysis of past hospital data to result in appropriate placement of the service for the upcoming year in an APC in which there is clinical integrity of the groups and weights. Therefore, we believe that the appropriate default, in the absence of a code that describes the service being furnished, is placement in the lowest level APC within the clinical category in which the unlisted code falls. We see no need to expand the process that is followed for physician payment of unlisted codes to the outpatient hospital setting. The assignment of the unlisted codes to the lowest level APC in the clinical category specified in the code provides a reasonable means for interim payment until such time as there is a code that specifically describes what is being paid. It encourages the creation of codes where appropriate and mitigates against overpayment of services that are not clearly identified on the bill. For new technologies that are complete services but may not have yet been granted a specific CPT code, the new technology payment mechanism is available under OPPS. Outlier payments may also be available under the OPPS in a case of an expensive new technology for which a specific code is not available and for which the costs of the new procedure exceed the outlier threshold.

Comment: One commenter indicated that the principal problem behind the use of unlisted or not otherwise classified codes is the AMA's bias against giving CPT codes for new services and technologies unless a physician group requests the code to provide a mechanism for increased physician payment for the service. The commenter asked that CMS, as the largest and most powerful licensee of CPT, influence the AMA to reduce the amount of time it takes to release new CPT codes for use in the OPPS so that the need for use of unlisted codes will diminish and the new services can be paid appropriately more quickly after they come onto the market. The commenter also asked that CMS reduce its ''barriers'' to placement of new services that require new technologies into new technology APCs or to granting of pass through payment status. The commenter indicated that lowering these ''barriers'' also would eliminate much of the use of the unlisted codes.

Response: An individual, a physician group, or a manufacturer may submit a request for a new CPT code. CMS works collaboratively with the AMA to establish new CPT codes, recognizing that the process is governed and controlled by the AMA. The AMA CPT process involves methodical consideration of new coding proposals, which may be time consuming. In addition, the payment system changes required by new codes take some time to implement. Under the OPPS, we make available the pass-through and new technology payment mechanisms, using C-codes and G-codes to allow new services, devices, and technologies to be available to clinicians and providers to facilitate appropriate payment for such services. The commenter did not indicate what ''barriers'' to placement of new services exist. However, to assist the public, we provide further guidance in section IV.C. of the preamble concerning additional comments on the topic of the surgical insertion or implantation criterion for the pass-through device payment mechanism.

In this final rule with comment period, we are adopting as final, without modification, the proposed reassignment of unlisted HCPCS codes to move all unlisted or ''not otherwise classified'' codes to the lowest level APC that is appropriate to the clinical nature of the service, as displayed in Table 15.

Table 15.--Reassignments of Unlisted HCPCS Codes

HCPCS Short Description	CY 2004 APC Assignment	CY 2005 APC Assignment
15999	0022	0019
21089	0253	0251
21299	0253	0251
21499	0253	0251
21899	0252	0251
22999	0022	0019
31299	0252	0251
31599	0254	0251
40799	0253	0251
40899	0252	0251
41899	0253	0251
42699	0253	0251
42999	0252	0251
47399	0037	0002
48999	0005	0004
49659	0131	0130
67599	0239	0238
67999	0240	0238
68399	0239	0238
68899	0699	0230
69799	0253	0251
69949	0253	0251

I. Addition of New Procedure Codes

During the first two quarters of CY 2004, we created 85 HCPCS codes that were not addressed in the November 7, 2003 final rule with comment period that updated the CY 2004 OPPS. We have designated the payment status of those codes and added them to the April and July updates of the 2004 OPPS (Transmittals 3144, 3154, 3322, and 3324). We showed these codes in Table 16 of the proposed rule. Thirty of the new codes were created to enable providers to bill for brand name drugs and to receive payments at a rate that differs from that for generic equivalents, as mandated in section 1833(t)(14)(A)(i) of the Act as added by Pub. L. 108–173. In the August 16, 2004 proposed rule, we solicited comment on the APC assignment of these services. Further, consistent with our annual APC updating policy, we proposed to assign the new HCPCS codes for CY 2005 to the appropriate APCs.

We did not receive any public comments on our proposal. Accordingly, in this final rule with comment period, we are adopting as final our proposal to assign the new HCPCS codes for CY 2005 to the appropriate APCs, as shown in Addendum B of this final rule with comment period, without modification.

J. OPPS Changes Relating to Coverage of Initial Preventive Physical Examinations and Mammography Services Under Pub. L. 108–173

1. Payment for Initial Preventive Physical Examinations (Section 611 of Pub. L. 108–173)

a. Background

Section 611 of Pub. L. 108–173 provides for coverage under Medicare Part B of an initial preventive physical examination for new beneficiaries, effective for services furnished on or after January 1, 2005. This provision applies to beneficiaries whose coverage period under Medicare Part B begins on or after January 1, 2005, and only for an initial preventive physical examination performed within 6 months of the beneficiary's initial coverage date.

Current Medicare coverage policy does not allow for payment for routine physical examinations (or checkups) that are furnished to beneficiaries. Before the enactment of Pub. L. 108–173, all preventive physical examinations had been excluded from coverage based on section 1862(a)(7) of the Act, which states that routine physical checkups are excluded services. This exclusion is specified in regulations under § 411.15(a). In addition, preventive physical examinations had been excluded from coverage based on section 1862(a)(1)(A) of the Act. This section of the Act provides that items and services must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (as implemented in regulations under § 411.15(k)).

Coverage of initial preventive physical examinations is provided only under Medicare Part B. As provided in the statute, this new coverage allows payment for one initial preventive physical examination within the first 6 months after the beneficiary's first Part B coverage begins, although that coverage period may not begin before

January 1, 2005. We also note that Pub. L. 108–173 did not make any provision for the waiver of the Medicare coinsurance and Part B deductible for the initial preventive physical examination. Payment for this service would be applied to the required Medicare Part B deductible, which is $110 for CY 2005, if the deductible has not been met, and the usual coinsurance provisions would apply.

b. Amendments to Regulations

In the August 16, 2004 proposed rule, we proposed to amend our regulations to add a new § 410.16 that would provide for coverage of initial preventive physical examinations in various settings, including the hospital outpatient department, as specified in the statute, and specify the condition for coverage and limitation on coverage. In addition, we proposed to conform our regulations on exclusions from coverage under § 411.15(a)(1) and § 411.15(k) to the provisions of section 611 of Pub. L. 108–173. Specifically, we proposed to specify an exception to the list of examples of routine physical checkups that are excluded from coverage under § 411.15(a) and to add a new exclusion under § 411.15(k)(11).

We proposed to amend § 419.21 of the OPPS regulations to add a new paragraph (e) to specify payment for an initial preventive physical examination as a Medicare Part B covered service under the OPPS if the examination is furnished within the first 6 months of the beneficiary's first Medicare Part B coverage.

We noted that the initial preventive physical examination was also addressed in detail in our proposed rule to update the Medicare Physician's Fee Schedule for CY 2005 (69 FR 47487, August 5, 2004). However, because we believe the same elements of the initial physical examination furnished in a physician's office would also apply when the examination is performed in a hospital outpatient clinic, we proposed to revise the applicable regulations to reflect this requirement.

Section 611(b) of Pub. L. 108–173 defines an ''initial preventive physical examination'' to mean physicians'' services consisting of—

(1) A physical examination (including measurement of height, weight, blood pressure, and an electrocardiogram (EKG), but excluding clinical laboratory tests) with the goal of health promotion and disease detection; and

(2) Education, counseling, and referral with respect to screening and other preventive coverage benefits separately authorized under Medicare Part B, excluding clinical laboratory tests.

Specifically, section 611(b) of Pub. L. 108–173 provides that the education, counseling, and referral services with respect to the screening and other preventive services authorized under Medicare Part B include the following:

(1) Pneumococcal, influenza, and hepatitis B vaccine and their administration;

(2) Screening mammography;

(3) Screening pap smear and screening pap smear and screening pelvic examination;

(4) Prostate cancer screening tests;

(5) Colorectal cancer screening tests;

(6) Diabetes outpatient self-management training services;

(7) Bone mass measurements;

(8) Screening for glaucoma;

(9) Medical nutrition therapy services for individuals with diabetes and renal disease;

(10) Cardiovascular screening blood tests; and

(11) Diabetes screening tests.

Section 611(d)(2) of Pub. L. 108–173 amended sections 1861(s)(2)(K)(i) and (s)(2)(K)(ii) of the Act to specify that the services identified as physicians' services and referred to in the definition of initial preventive physical examination include services furnished by a physician assistant, a nurse practitioner, or a clinical nurse specialist. We refer to these professionals as ''qualified nonphysician practitioners.''

Based on the language of the statute, our review of the medical literature, current clinical practice guidelines, and United States Preventive Services Task Force recommendations, we proposed (under proposed new § 410.16(a), Definitions) to interpret the term ''initial preventive physical examination'' for purposes of this new benefit to include all of the following services furnished by a doctor of medicine or osteopathy or a qualified nonphysician practitioner:

(1) Review of the beneficiary's comprehensive medical and social history. We proposed to define ''medical history'' to include, as a minimum, past medical and surgical history, including experience with illnesses, hospital stays, operations, allergies, injuries, and treatments; current medications and supplements, including calcium and vitamins; and family history, including a review of medical events in the patient's family, including diseases that may be hereditary or place the individual at risk. We proposed to define ''social history'' to include, at a minimum, history of alcohol, tobacco, and illicit drug use; work and travel history; diet; social activities; and physical activities.

(2) Review of the beneficiary's potential (risk factors) for depression (including past experiences with depression or other mood disorders) based on the use of an appropriate screening instrument that the physician or qualified nonphysician practitioner may select from various available standardized screening tests for this purpose, unless the appropriate screening instrument is defined through the national coverage determination (NCD) process.

(3) Review of the beneficiary's functional ability and level of safety (that is, at a minimum, a review of the following areas: Hearing impairment, activities of daily living, falls risk, and home safety), based on the use of an appropriate screening instrument, which the physician or qualified nonphysician practitioner may select from various available standardized screening tests for this purpose, unless the appropriate screening instrument is further defined through the NCD process.

(4) An examination to include measurement of the beneficiary's height, weight, blood pressure, a visual acuity screen, and other factors as deemed appropriate, based on the beneficiary's comprehensive medical and social history and current clinical standards.

(5) Performance of an electrocardiogram and interpretation.

(6) Education, counseling, and referral, as deemed appropriate, based on the results of elements (1) through (5) of the definition of the initial preventive physical examination.

(7) Education, counseling, and referral, including a written plan for obtaining the appropriate screening and other preventive services, which are also covered as separate Medicare Part B benefits; that is, pnuemococcal, influenza, and hepatitis B vaccines and their administration, screening mammography, screening pap smear and screening pelvic exams, prostate cancer screening tests, diabetes outpatient self-management training services, bone mass measurements, screening for glaucoma, medical nutrition therapy services, cardiovascular screening blood tests, and diabetes screening tests.

As we indicated in the OPPS proposed rule, we are addressing the public comments that we received on our proposal to revise our regulations to include specific coverage of initial preventive physical examinations under Medicare Part B and finalizing our coverage policy for initial preventive physical examinations in the final rule for the CY 2005 Medicare Physician Fee

Schedule published elsewhere in this issue.

c. Assignment of New HCPCS Codes for Payment of Initial Preventive Physical Examinations

There was no CPT code that contained the specific elements included in the initial preventive physical examination. Therefore, in the August 16, 2004 proposed rule, we proposed to establish a new HCPCS code to be used to bill for the new service under both the Medicare Physician Fee Schedule and the OPPS. We proposed a code, GXXXX, for the full service, including an EKG, but not including the other previously mentioned preventive services that are currently separately covered and paid under the Medicare Part B screening benefits. When these other preventive services are performed, they should be billed using the existing appropriate HCPCS and CPT codes.

For payment under the Medicare Physician Fee Schedule, relative value units were proposed for the new HCPCS code for the initial preventive physical based on equivalent resources and work intensity to those contained in CPT evaluation and management code 99203 (New patient, office or other outpatient visit) and CPT 93000 (Electrocardiogram, complete) (69 FR 47487, August 5, 2004). The ''technical component'' of the Medicare Physician Fee Schedule (the costs other than those allocated for the physician's professional services and professional liability insurance which are billed and paid for separately, when appropriate) is the portion of the fee schedule payment that is most comparable to what Medicare pays under the OPPS. The estimated ''technical component'' of the Medicare Physician Fee Schedule payment for GXXXX was between $50 and $100.

d. APC Assignment of Initial Preventive Physical Examination

Given our lack of cost data to guide assignment of the new code to a clinically appropriate APC, in our proposed rule, we proposed assignment of the new code GXXXX (Initial preventive physical examination) to New Technology APC 1539 (New Technology, Level II) with a payment level between $50 and $100. We believed that the proposed temporary assignment to a new technology APC would allow us to pay for the new benefit provided in the OPD while we accrued claims data and experience on which to base a clinically relevant APC assignment in the future.

We received a number of public comments regarding the proposed payment for the initial preventive physical examination and its proposed APC placement.

Comment: A number of commenters highlighted billing and operational concerns with the definition of a single HCPCS code, GXXXX, for the initial preventive physical examination. The commenters explained that, in hospitals where the EKG was performed in a separate department from the location of the physical examination, the technician charging for the service would have no way of distinguishing an EKG related to the initial preventive physical examination from other EKG tracings performed for diagnostic purposes, for which the hospital would bill for that specific service. The commenters noted that physicians often send their patients to hospitals for the EKG tracing, and if hospitals performed the EKG associated with the initial preventive physical examination in this context, they would have no way to bill for the EKG. The commenters presented various alternative coding possibilities for our consideration to address these situations.

Response: Section 611 of Pub. L. 108–173 does require a screening EKG to be performed as part of the initial preventive physical examination visit. In view of the different circumstances that may occur when performing the full initial preventive physical examination, we are establishing four new G codes for the initial preventative physical examination for CY 2005.

- G0344: Initial preventive physical examination; face-to-face visit, services limited to new beneficiary during the first 6 months of Medicare Part B enrollment. This code is assigned a status indicator ''V'' for the OPPS.
- G0366: Electrocardiogram, routine EKG with at least 12 leads; performed as a component of the initial preventive physical examination with interpretation and report. This code is assigned a status indicator ''B'' for the OPPS.
- G0367: Electrocardiogram, tracing only, without interpretation and report, performed as a component of the initial preventive physical examination. This code is assigned status indicator ''S'' for the OPPS.
- G0368: Electrocardiogram, interpretation and report only, performed as a component of the initial preventive physical examination. This code is assigned status indicator ''A'' for the OPPS.

In the hospital, performance of the complete initial preventive physical examination service would be coded using both the G0344 and G0367 codes. As required by the statute, the new codes describe the visit and the EKG, but not the other previously mentioned preventive services that are currently separately covered and paid under the Medicare Part B screening benefits. When these other preventive services are performed, they should be billed using the existing appropriate HCPCS and CPT codes.

To comply with Pub. L. 108–173, the initial preventive physical examination must include the EKG, regardless of whether a diagnostic EKG had previously been performed. Both components of the initial preventive physical examination, the examination and the EKG, must be performed to fulfill the statutory benefit for either of the components to be paid. Billing instructions for providers will be issued.

In addition to our decision to create two codes for hospitals to report for performance of the initial preventive physical examination service, we are assigning the codes to appropriate APCs as follows: G0344 is assigned to APC 0601 (Mid Level Clinic Visits), and G0367 is assigned to APC 0099 (Electrocardiograms). These APC assignments result in a total payment of approximately $78, slightly more than the $75 payment rate proposed for the comprehensive initial preventive physical examination service in the proposed rule.

Comment: A few commenters requested that CMS increase the payment for the initial preventive physical examination benefit and stated that the payment rate set is too low to cover the required clinical resources.

Response: As stated in our proposed rule, the payment rate for the comprehensive initial preventive physical examination service under the OPPS was based on the rate proposed under the Medicare Physician Fee Schedule, which utilized estimates of necessary resources for the initial preventive physical examination benchmarked against the resources required to deliver existing evaluation and management and electrocardiogram services in the physician office. Based on comments concerning the adequacy of our proposed payment for the comprehensive initial preventive physical examination service and our decision to separate the examination service from the EKG for coding and payment purposes, we explicitly compared the resources we anticipated for the examination service delivered in the hospital to the OPPS median cost for the existing new office or other outpatient visit service which was used as a crosswalk. CPT code 99203 (Office

or other outpatient visit for a new patient) is in APC 0601, which has a median cost of $57.66. The AMA/Specialty Society RVS Update Committee survey data for code 99203 showed 51 minutes of staff time, and we believe the initial preventive physical examination will reflect comparable time and consumption of hospital resources. As we expect the hospital resources utilized for code G0344 to be similar to those needed for clinic visits for which we have historical hospital cost data, we will place G0344 in APC 0601 rather than in a new technology APC as we proposed for the initial preventive physical examination comprehensive service. We expect the hospital resources utilized for the screening EKG tracing, code G0367, to be very similar to those necessary for a diagnostic EKG tracing, code 93005 and assigned to APC 0099. Together these APCs (0601 and 0099) will pay approximately $78, several more dollars than we proposed for the comprehensive service. We will monitor our claims data for the initial preventive physical examination services as hospitals gain experience delivering the services. We are finalizing our placement of code G0344 in APC 0601 for CY 2005 and code G0367 in APC 0099 for 2005.

Comment: Several commenters asked that CMS provide explicit instructions and guidelines, respectively, to providers and beneficiaries regarding the details of what will be included in the new initial preventive physical examination benefit, the eligibility requirements, and how providers should bill Medicare for the new service. One commenter asked if the preventive physical examination will be subject to the evaluation and management guidelines.

Response: We will release appropriate manual and transmittal instructions and information from the CMS educational components for the medical community, including a MedLearn Matters article and fact sheets such as the ''2005 Payment Changes for Physicians and Other Providers: News From Medicare for 2005''. The medical community can join this effort in educating physicians and beneficiaries by their own communications, bulletins, or other publications. In addition, we have specifically included information on the new initial preventive physical examination benefit in the 2005 version of the *Medicare and You Handbook* and revised booklet, *Medicare's Preventive Services*. A new 2-page fact sheet on all of the new preventive services, including the initial preventive physical examination benefit, will be available this Fall, and a bilingual brochure for Hispanic beneficiaries will also be available in the near future. Information will be disseminated by CMS regional offices, State Health Insurance Assistance Programs (SHIPs), and various partners at the national, State, and local levels. Information on the new benefit will also be made available to the public through Web site, *http://www.medicare.gov*, the partner Web site to *http://www.cms.hhs.gov*, the toll free number 1–800–MEDICARE, numerous forums hosted by CMS, and conference exhibits and presentations.

The initial preventive physical examination will not be subject to each hospital's internal set of evaluation and management guidelines that hospitals were instructed to develop at the implementation of the OPPS in the August 7, 2000 final rule (65 FR 18451) because we have defined one explicit service, without levels.

Comment: Several commenters asked how providers of initial preventive physical examination services will know if a particular beneficiary is eligible to receive the new benefit due to the statutory time and coverage frequency (one-time benefit) limitations.

Response: The statute provides for coverage of a one-time initial preventive physical examination that must be performed for new beneficiaries by qualified physicians or certain specified nonphysician practitioners within the first 6 month period following the effective date of the beneficiary's first Medicare Part B coverage. Because physicians or qualified nonphysician practitioners may not have the complete medical history for a particular new beneficiary, including information on possible use of the one-time benefit, these clinicians are largely relying on their own medical records and the information the beneficiary provides to them in establishing whether or not the initial preventive physical examination benefit is still available to a particular individual and has not been performed by another qualified practitioner. Because a second initial preventive physical examination will always fall outside the definition of the new Medicare benefit, an advance beneficiary notice (ABN) need not be issued in those instances where there is doubt regarding whether the beneficiary has previously received an initial preventive physical examination. The beneficiary will always be liable for a second initial preventive physical examination, no matter when it is conducted. However, for those instances where there is sufficient doubt as to whether the statutory 6-month period has lapsed, the physician or qualified nonphysician practitioner should issue an ABN to the beneficiary that indicates that Medicare may not cover and pay for the service. If the physician or qualified nonphysician practitioner does not issue an ABN to the beneficiary and Medicare denies payment for the service because the statutory time limitation for conducting the initial preventive physical examination has expired, the physician or qualified nonphysician practitioner may be held financially liable.

Comment: One commenter recommended that CMS compare the requirements of the initial preventive physical examination to the contemplated requirements for similar but not-yet-disclosed facility-specific evaluation and management level definitions. The commenter wanted to ensure that the technical requirements are comparable between the new benefit and similar evaluation and management service definitions being contemplated by CMS.

Response: We will take the commenter's recommendation into consideration in our ongoing work to develop new evaluation and management codes for the OPPS.

2. Payment for Certain Mammography Services (Section 614 of Pub. L. 108–173)

Section 614 of Pub. L. 108–173 amended section 1833(t)(1)(B)(iv) of the Act to provide that screening mammography and diagnostic mammography services are excluded from payment under the OPPS. This amendment applies to screening mammography services furnished on or after December 8, 2003 (the date of the enactment of Pub. L. 108–173), and in the case of diagnostic mammography, to services furnished on or after January 1, 2005. As a result of this amendment, both screening mammography and diagnostic mammography will be paid under the Medicare Physician Fee Schedule.

In the August 16, 2004 proposed rule, we proposed to amend § 419.22 of the regulations by adding a new paragraph(s) to specify that both screening mammography and diagnostic mammography will be excluded from payment under the OPPS, in accordance with section 614 of Pub. L. 108–173. We received a few public comments on our proposal.

Comment: A few commenters expressed support for the movement of payment for diagnostic mammograms from the OPPS to the Medicare Physician Fee Schedule.

Response: We appreciate the commenters' support. Additional

discussion of section 614 of Pub. L. 108–173 can be found in the final rule for the CY 2005 Medicare Physician Fee Schedule published elsewhere in this issue.

Comment: A few commenters recommended that the payment rates for mammography be increased. The commenters stated that beneficiary access to mammography is being limited due to a growing number of radiologists who refuse to read mammograms due to low payment and high malpractice rates and recent closure of a large number of centers across the country.

Response: We set the payment rates for diagnostic mammography based on hospital claims data, consistent with the payment methodology for OPPS services. In fact, in accordance with section 614 of Pub. L. 108–173, which requires that diagnostic mammography be paid now under the Medicare Physician Fee Schedule, payment is set using an entirely different process. This statutory change in the payment process results in a somewhat increased payment for mammography procedures from that under the OPPS.

Comment: One commenter asked CMS to clarify that the increase in payment for diagnostic mammography furnished in the hospital outpatient department does not ''come out of the [Medicare Physician Fee Schedule] budget.''

Response: The increase in payment for diagnostic mammography furnished in the hospital outpatient department has no effect on payment for Medicare Physician Fee Schedule services. We are using the Medicare Physician Fee Schedule rate to set Medicare payment for diagnostic mammography furnished in the hospital outpatient department, as required by statute. Further, we are not including diagnostic mammography in our model for setting the relative weights under the OPPS. Thus, the increase in payment for diagnostic mammography furnished in the hospital outpatient department also has no effect on payment for any other OPPS services.

In this final rule, we are adopting, as final without modification, our proposed revision of § 419.22 to incorporate the provisions of section 614 of Pub. L. 108–173.

III. Recalibration of APC Relative Weights for CY 2005

A. Database Construction

Section 1833(t)(9)(A) of the Act requires that the Secretary review and revise the relative payment weights for APCs at least annually, beginning in CY 2001 for application in CY 2002. In the April 7, 2000 OPPS final rule (65 FR 18482), we explained in detail how we calculated the relative payment weights that were implemented on August 1, 2000, for each APC group. Except for some reweighting due to APC changes, these relative weights continued to be in effect for CY 2001. This policy is discussed in the November 13, 2000 interim final rule (65 FR 67824 through 67827).)

In the August 16, 2004 OPPS proposed rule, we proposed to use the same basic methodology that we described in the April 7, 2000 final rule to recalibrate the relative APC weights for services furnished on or after January 1, 2005, and before January 1, 2006. That is, we proposed to recalibrate the weights based on claims and cost report data for outpatient services. We proposed to use the most recent available data to construct the database for calculating APC group weights. We provide a complete description of the data processes we proposed to use for the creation of the CY 2005 OPPS payment rates in the August 16, 2004 proposed rule (69 FR 50448).

For the purpose of recalibrating APC relative weights for CY 2005 displayed in this final rule with comment period, we used the most recent available claims data, which were the approximately 132 million final action claims for hospital OPD services furnished on or after January 1, 2003, and before January 1, 2004. Of the 132 million final action claims for services provided in hospital outpatient settings, 106 million claims were of the type of bill potentially appropriate for use in setting rates for OPPS services (but did not necessarily contain services payable under the OPPS). Of the 106 million claims, we were able to use 51 million whole claims (from which we created 84 million single procedure claim records) to set the final OPPS CY 2005 APC relative weights. We used claims from this period that had been processed before June 30, 2004, to calculate the APC weights and payments contained in Addenda A and B of this final rule with comment period.

We received one general public comment on our proposed OPPS database construction for CY 2005 discussed in the August 16, 2004 proposed rule.

Comment: One commenter suggested that CMS use a nationally representative sample of hospitals from which cost data could be collected for purposes of setting relative weights. The commenter suggested that such a sample could be used to validate findings from the larger claims data set or to establish median costs that more accurately reflect the costs of providing device-related procedures and other outpatient services, or both. As an alternative, the commenter suggested conducting a demonstration project using a sample of hospitals that would receive small grants for set up and training to test the feasibility of collecting a valid reliable and manageable data set from which to develop payment rates.

Response: We believe that the Medicare hospital outpatient claims and hospital cost reports are the best, nationally representative database of such information at present. Nevertheless, we acknowledge that an approach that would involve the collection of additional hospital data from a representative sample could have some merit. However, in addition to the resources that would be required for us to pursue such an approach, we also are concerned about the costs to hospitals associated with such an additional data collection effort. Nevertheless, we remain interested and invite additional suggestions from hospitals and other stakeholders on ways to enhance the data we now use to set relative weights for services paid under the OPPS.

1. Treatment of Multiple Procedure Claims

For CY 2005, we proposed to continue to use single procedure claims to set the medians on which the weights would be based (69 FR 50474). As indicated in the August 16, 2004 proposed rule, we received many requests that we ensure that the data from claims that contain charges for multiple procedures were included in the data from which we calculate the CY 2005 relative payment weights (69 FR 50474). Requesters believe that relying solely on single procedure claims to recalibrate APC relative weights fails to take into account data for many frequently performed procedures, particularly those commonly performed in combination with other procedures. They believe that, by depending upon single procedure claims, we base relative payment weights on the least costly services, thereby introducing downward bias to the medians on which the weights are based.

We agree that, optimally, it is desirable to use the data from as many claims as possible to recalibrate the relative payment weights, including those with multiple procedures. As discussed in the explanation of single procedure claims below, we have used the date of service on the claims and a list of codes to be bypassed to create ''pseudo'' single claims from multiple procedure claims. We refer to these newly created single procedure claims